UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

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UNITED STATES OF AMERICA, et al,

Plaintiffs,

v.

JOHNSON & JOHNSON, JANSSEN PRODUCTS, L.P.

Defendants.
_____

CIVIL ACTION NUMBER:

3:12-cv-07758-ZNQ-JBD

JURY TRIAL - VOLUME 15

Clarkson S. Fisher Building & U.S. Courthouse
402 East State Street
Trenton, New Jersey 08608
June 3, 2024
Commencing at 8:30 a.m.

B E F O R E: THE HONORABLE ZAHID N. QURAISHI,
                                     UNITED STATES DISTRICT JUDGE

A P P E A R A N C E S:

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      produced by computer-aided transcription.

United States District Court
District of New Jersey

1   **I N D E X**

2   **EXAMINATIONS**   **PAGE**

3

              PROFESSOR ISRAEL SHAKED
4   DIRECT EXAMINATION BY MR. MARKETOS   5398
     CROSS-EXAMINATION BY MS. BROWN   5497
5   REDIRECT EXAMINATION BY MR. MARKETOS   5594
              MEGAN MCGRATH
6   DIRECT EXAMINATION BY BY MS. BROWN   5636
     CROSS-EXAMINATION BY MR. RUSS   5653
7   REDIRECT EXAMINATION BY MS. BROWN   5668
              KIMBERLY SALADANA
8   DIRECT EXAMINATION BY MR. KLEIN   5671

9   **E X H I B I T S**

10

11   **Exhibit No.**   **Description**   **Page**

12   Defendants' Exhibit 3005 in   5517
         evidence.
13   Defendants' Exhibit 4006 in   5677
         evidence.
14   Defendants' Exhibit 4019 in   5682
         evidence.
15   Defendants' Exhibit 4123 in   5688
         evidence.
16   Defendants' Exhibit 4131 in   5705
         evidence.
17   Defendants' Exhibit 4066 in   5712
         evidence.
18   Defendants' Exhibit 4187 in   5716
         evidence.

19

20

21

22

23

24

25

United States District Court
District of New Jersey

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 1              (PROCEEDINGS held in open court before The Honorable

 2   ZAHID N. QURAISHI, United States District Judge, on June 3,

 3   2024, at 8:30 a.m.)

 4              THE DEPUTY COURT CLERK:  All rise.

 5              THE COURT:  All right, folks.  You may have a seat.

 6   Thank you.

 7          Let's have appearance from counsel beginning with

 8   Relators.

 9              MR. MARKETOS:  Good morning, Your Honor.

10   Pete Marketos for the Relators.

11              MS. WENDEL:  Good morning.  Whitney Wendel for

12   Relators.

13              MR. WIRMANI:  Good morning, Judge.  Andrew Wirmani

14   for Relators, Judge.

15              MR. RUSS:  Good morning.  Josh Russ for Relators.

16              THE COURT:  All right.  Good morning, folks.

17              MS. BROWN:  Good morning, Your Honor.  Alli Brown for

18   Janssen.

19              MR. WYATT:  Good morning, Your Honor.  Geoff Wyatt

20   for Janssen.

21              MR. KLEIN:  Good morning.  Brad Klein for Janssen.

22              THE COURT:  All right.  Good morning, everybody.

23          So where should I begin?  Let me ask you this.  I

24   haven't read the submissions.  I just started to put eyes on

25   them this morning so I haven't even read them in any detail,
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United States District Court
District of New Jersey

1   but just a quick, cursory review, is it my understanding from

2   Janssen that additional documents have been produced to

3   Relators? And when were they produced, and how many documents

4   are we talking about?

5   MR. WYATT: There's 20 that were produced yesterday,

6   18 of which around 4 p.m., two later in the day, and a

7   privileged log of 25 additional documents.

8   THE COURT: And those documents all pertain to the

9   compliance investigation?

10   MR. WYATT: I -- yes. I believe so, yes.

11   THE COURT: All right.

12   And, then, am I going to get a copy of what those

13   documents are?

14   MR. WYATT: Yes. We can provide the Court with a

15   copy.

16   THE COURT: Yeah, I want to see those as well. I

17   mean, I've looked at documents that were provided in camera,

18   but I want to see what additional documents were produced to

19   Relators since that time.

20   And then let me review that. I'll review your

21   submissions, and we'll probably either tomorrow or Wednesday

22   talk about that issue some more. But I'm not prepared to

23   speak about it this morning since I really want to review what

24   you've all submitted Sunday to get your arguments there.

25   Is there anything more that we need to talk about? I

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 1   know I'm tabling the issue, but is there anything more that
 2   happened since last week other than these additional documents
 3   that were produced?
 4          MR. WYATT:  No, Your Honor.  I think -- I mean,
 5   everything that's happened has been sort of set forth in the
 6   letters --
 7          THE COURT:  Okay.
 8          MR. WYATT:  -- so there's nothing new to report.
 9          THE COURT:  That's what I meant, there's nothing new.
10   And that was already identified in the letter, and that's what
11   I saw there.
12          MR. WYATT:  Correct.  And just to speak to the
13   Court's questions from last week, and the letter spells out
14   what we did, but we did undertake a very sensitive effort to
15   look for additional documents, and we've sort of set forth --
16   rather than recite it here, I'll just refer the Court to the
17   letter, if that's okay.
18          THE COURT:  That's fair.
19          MR. WYATT:  It explains what we did.
20          THE COURT:  Mr. Marketos, anything additional, then,
21   other than me at least getting eyes on what documents you
22   received most recently?  Because I have your submission as
23   well.
24          MR. MARKETOS:  Yes, Your Honor.  Nothing more.
25          THE COURT:  All right.
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United States District Court
District of New Jersey

1   MR. MARKETOS: And we'll need to review their --

2   we're just digesting what they filed this morning.

3   THE COURT: Right. There were simultaneous

4   submissions. You're both reviewing what each side -- all

5   right. I don't need any replies.

6   If there's anything more, you guys can raise it in open

7   court when we speak, but I don't need any more submissions.

8   Like I said, I haven't reviewed them in any detail. I did a

9   cursory review to see if there was something we needed to

10   speak about this morning. The only issue I saw was getting

11   eyes on these additional documents. Okay?

12   MR. WYATT: And sorry. One point of clarification on

13   that, Your Honor. Would you like to see in camera the 25

14   privileged documents as part of that?

15   THE COURT: Oh, I see. So there's additional

16   documents that were produced and additional documents that

17   were placed on the log.

18   MR. WYATT: 20 produced; 25 on the log.

19   THE COURT: I'll need to see both. Obviously, the

20   privileged documents I'm only to review in camera.

21   MR. WYATT: Of course.

22   THE COURT: I'm not going to discuss yet until we

23   figure it out.

24   Okay. So I can get those by the lunch break or

25   sometime --

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 1              MR. WYATT:  I'll get started on this right away.

 2   Certainly, by the end of the day, but hopefully by lunch.

 3              THE COURT:  Okay.  All right.  Thank you.

 4         One other issue I had for housekeeping is June 12th is

 5   back.  So I know we were not going to sit June 12th.  My

 6   understanding, then -- and, Ms. Brown, you correct me if I'm

 7   wrong -- is that Janssen will get the case at some point

 8   today, you guys will rest on the 11th, and then the parties

 9   will be prepared, and I'll have to be prepared, with final

10   instructions on the 12th rather than the 13th.

11         Does that make sense?

12              MS. BROWN:  That's right, Your Honor.

13              THE COURT:  All right.  So at some point -- I'm going

14   through the final instructions now.  My understanding is there

15   may be some additional instructions that were submitted with

16   these most recent submission.

17         Mr. Wyatt, you have something on that?

18              MR. WYATT:  Just to speak on that point very briefly,

19   Your Honor.  I know everyone's been very busy this weekend,

20   and so as a result of those efforts, we did get proposed

21   instructions from Relators last night.  It was relatively

22   late, so we didn't have a time to respond.  But we will put a

23   response -- we're not proposing our own instructions.  We're

24   just responding to the ones that they're proposing --

25              THE COURT:  Okay.
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1	MR. WYATT: -- potential alterations. We will file
2	that tonight.
3	THE COURT: All right. So I'll have that. Okay.
4	That's fair.
5	So you haven't -- in your submission, you haven't
6	addressed these additional instructions from Relators. You're
7	going to address them, but you don't have some counterproposal
8	for an instruction. You're just addressing whether these
9	instructions should be included or not.
10	MR. WYATT: Our initial position is they shouldn't be
11	included. We may suggest that, if they're going to be
12	included, they should have some additional language. But
13	we're not proposing our own separate instructions, so we
14	didn't --
15	THE COURT: All right.
16	MR. WYATT: -- feel like we needed -- we felt like we
17	needed to see what they were proposing before we could react
18	to it last night.
19	THE COURT: Understood.
20	MR. WYATT: It was just so late, we didn't respond.
21	THE COURT: I'll get it tonight.
22	MR. WYATT: Okay. Yes.
23	THE COURT: Mr. Marketos, just to remind me, though,
24	how many instructions did you propose? Was it two or three?
25	MR. MARKETOS: Two, Your Honor.

1   THE COURT: And what -- just give me the subject

2   matter. I don't need the instruction.

3   MR. MARKETOS: Silence by the FDA is not approval was

4   one of them, and then with respect to the Relators gathering

5   of documents --

6   THE COURT: Gathering of documents.

7   MR. MARKETOS: -- is protected by -- yes.

8   THE COURT: Those are both issues you raised last

9   week that you were going to submit.

10   MR. MARKETOS: Yes, Your Honor.

11   THE COURT: All right. Well, I don't see any issue

12   with Janssen responding. Why don't you all respond by

13   tonight. I'll at least have that.

14   My threshold issue, though, is dealing with the

15   discovery issue and the waiver of privilege and all of that.

16   So I'll get to the jury instructions when I get to them. I'm

17   still reviewing the proposed final instructions that you all

18   submitted at the outset of the case. So I'm going through

19   those, and that will take at least a few days this week, if

20   not this week. But I'll have a good sense of where these

21   final instructions are going by the end of the week.

22   And if I -- at some point, I'll sit down with you folks

23   and kind of give my sense of where I am on those. But outside

24   of that and June 12th, we're going to be sitting.

25   Any other housekeeping issues that need to be raised

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 1  this morning?  Let me ask in order first.

 2          MR. MARKETOS:  No, Your Honor.  We're just ready to

 3  go.

 4          THE COURT:  You have one witness that is going to

 5  be -- is it Professor Shaked?

 6          MR. MARKETOS:  Professor Shaked, yes.

 7          THE COURT:  Shaked, okay.

 8      And that's your last witness, other than having the

 9  right to examine -- complete your examination of Ms. Kaucher

10  at a later date.

11          MR. MARKETOS:  Yes, Your Honor.  And then, to be

12  frank, because of this issue and the delay of Ms. Kaucher and

13  what's gone on, I think we're going to say we reserve -- we

14  rest, but we reserve -- it's a very kind of an odd

15  circumstance because we've got a witness that's still left to

16  be called.

17      So I think we will essentially rest our case, but

18  there's still a portion of it that's left open.

19          THE COURT:  With respect to only Ms. Kaucher.

20          MR. MARKETOS:  With respect to only Ms. Kaucher.

21          THE COURT:  That's fine.

22      It's been very clear on the record that you're going to

23  have the opportunity to examine Ms. Kaucher if you choose to

24  do so, and we're going to pick some later date to do that.

25          My understanding is the only reason we've tabled it is
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United States District Court
District of New Jersey

      1   because you have to have an understanding of what documents

      2   I'm going to order produced or not produced before you

      3   complete that examination. Correct?

      4   MR. MARKETOS: Yes, Your Honor.

      5   THE COURT: All right. So however you want to couch

      6   it is fine. I think we've alerted the jurors that Ms. Kaucher

      7   was temporarily excused; that she will be called back at a

      8   later date.

      9   And I think even when I summarize for them where we

     10   were logistically in the trial, that you all were expected to

     11   rest today --

     12   MR. MARKETOS: Correct.

     13   THE COURT: -- with that one caveat that Ms. Kaucher

     14   may be coming back.

     15   MR. MARKETOS: That's right.

     16   THE COURT: All right. So I don't think that's

     17   anything new to the jury, but if you want to rest with those

     18   words or something that paraphrases there, just don't make any

     19   indication that the reason why you're reserve on Ms. Kaucher

     20   is because you just received some documents.

     21   MR. MARKETOS: Right.

     22   THE COURT: Don't go into the discovery issue in

     23   front of this jury. I mean, I'll deal with that with you all,

     24   and if there's something I'm going to tell them about that, it

     25   will come from me. Okay?

1   MR. MARKETOS: Yes, Your Honor.

2   THE COURT: Mr. Wyatt, what else from Janssen?

3   Anything we need to speak about this morning?

4   MR. WYATT: Just one housekeeping sort of plan for

5   the day issue. We are going to move for a Rule 50 at the end

6   of -- or with the proviso it stays open for Ms. Kaucher -- at

7   the end of Relators' case. We're not filing a written brief,

8   and actually, we didn't put this on the record previously, so

9   I'll just do it now.

10   I think we had a discussion about this last Thursday,

11   and we agreed that we could preserve our rights under Rule 50

12   by orally moving, by orally making that motion at the

13   conclusion of Relators' case, and, again, I believe at the

14   conclusion of our case, and then there was going to be a

15   written submission, if necessary, after a verdict under

16   Rule 50(b) for judgment notwithstanding the verdict.

17   Is that -- is that the Court's recollection --

18   THE COURT: That's my understanding as well.

19   My only concern, though, is Mr. Marketos makes it

20   fairly clear that he's not completely resting the Relators'

21   case at this point, right, that he still has Ms. Kaucher. So

22   isn't it more proper for you to raise the motions after

23   they've at least had the right to either examine Ms. Kaucher

24   or state on the record that they no longer intend to examine

25   her, which I highly doubt that's going to happen.

United States District Court
District of New Jersey

1   But I presume that that's the appropriate time.

2 Because what I don't want to do is give an indication to the

3 jury, the Relators have not rested, but, wait, they have

4 rested. Which one is it. Right?

5   So right now they're resting with one contingency,

6 which is they still have the ability to examine Ms. Kaucher.

7 And I think until they either examine that witness or state on

8 the record before counsel and the Court, we're done. And that

9 may happen, you know, a few days into your case. That's when

10 I think you should raise the motion.

11   Any disagreement there?

12   MR. WYATT: None at all, Your Honor, as long as we're

13 preserving this and this is the Court's preference on how to

14 proceed.

15   So unless the Relators have an issue with that, we're

16 fine to proceed that way.

17   THE COURT: Mr. Marketos?

18   MR. MARKETOS: I don't have an issue with that in

19 terms of order of operations, Your Honor. I just wanted to

20 clarify it. When we're talking about making an oral motion,

21 the bases for the motion itself are going to be stated orally,

22 at least, so we understand what those bases are, right, not

23 just we move for Rule 50?

24   THE COURT: Yeah. I mean, I think you can just

25 briefly summarize, you know, the basis for your motion. And

United States District Court
District of New Jersey

 1   I'm going to say -- my inclination is to reserve on the motion

 2   so the parties have some opportunity to brief this in writing.

 3   And if you want to say something very briefly,

 4   Mr. Marketos, in response, that the Relators opposed the

 5   motion -- that's me. My apologies -- that the Relators oppose

 6   the motion, that's fine. We'll have a record that they intend

 7   to detail it in writing. You're going to intend to impose it

 8   in writing. And I'm, on the record, stating I'm reserving my

 9   decision and directing you all to brief this at a later date

10   since I don't want to slow down the trial for purposes of that

11   motion.

12   MR. MARKETOS: Very good, Your Honor. I was just

13   making sure the grounds for the motion will be --

14   THE COURT: I think that's fair. I think that's

15   fair.

16   So, Mr. Wyatt, when you guys get to that point,

17   whenever that may be, it may not necessarily be today, but

18   when we get to the point where I'm basically going to the

19   Relators after resolving these disputes and saying, When do

20   you intend to call -- to have Ms. Kaucher come back or do you

21   not intend to question her, at that point, why don't you raise

22   it.

23   MR. WYATT: We're on the same page, Your Honor.

24   Actually, that's what prompted me to speak, is because I do

25   intend to state the grounds for the motion, and there are

1 several of them, so it may take, like, 20 minutes or so.

2   THE COURT: That's fine.

3   MR. WYATT: So when we get there, maybe we can talk

4 about doing it first thing in the morning or last thing during

5 the day, I mean, just to keep the things moving while the

6 jury --

7   THE COURT: Yeah. I mean, it doesn't necessarily

8 need to be raised in front of the jury.

9   MR. WYATT: Correct.

10   THE COURT: It's not an issue for the jury.

11   So why don't we just say this: At some point this

12 week, I'm going to have to resolve the discovery issues and

13 what's getting turned over and what's not and whether there's

14 an instruction that's being given to the jury.

15   So once I resolve those issues, I think at that point

16 it would make sense for you to raise it outside of the jury.

17 So we can either do that in the morning, during a housekeeping

18 kind of time period or at the end of the day when we dismiss

19 the jurors for another, you know -- I don't expect it will

20 take more than 30 minutes to address this on both sides. No?

21   MR. WYATT: No.

22   THE COURT: Probably less. Okay.

23   So why don't we do that. And that way we're not

24 slowing down witness testimony or cutting into the defense

25 time with the motion.

United States District Court
District of New Jersey

1   MR. WYATT: Perfect.

2   And just one other, if I may, Your Honor.

3   THE COURT: Yeah.

4   MR. WYATT: We raised previously the possibility --

5   we anticipated moving to strike Professor Shaked's testimony

6   because it won't -- the assumptions that are necessary to

7   support haven't been established in the case.

8   We will see how his testimony comes in, and then we

9   will decide if it makes sense to make that motion. I do

10   anticipate that we will, but I want to see what the testimony

11   says first.

12   THE COURT: And are you saying that this is going to

13   be something more than what I already determined in the motion

14   in limine?

15   MR. WYATT: It is. And we'll set that forth.

16   I think the best way to do this is rather than make the

17   argument orally at the end, to kind of do what we're doing

18   with Rule 50. We'll put in a written motion very quickly. As

19   soon as we have the transcript, it can plug in those cites.

20   And then you'll see the bases for the motion and sort of the

21   legal authority for separating it from the pretrial motion,

22   and the Relators will have an opportunity to respond, and I

23   think that is probably the most efficient way to proceed.

24   THE COURT: When do I get that?

25   MR. WYATT: As soon as we have the transcript,

 1 you'll --

 2   THE COURT: I mean, he's going to complete his

 3 testimony today. So we'll have a transcript at some point.

 4 So you think sometime tomorrow I'm going to see that?

 5   MR. WYATT: Tomorrow for sure. I mean, if we get it

 6 early enough tonight, maybe even late tonight. It just

 7 depends on when we get that transcript.

 8   THE COURT: And then, Mr. Marketos, how much time

 9 would you need to respond to that?

10   MR. MARKETOS: Who knows, Your Honor. Maybe he

11 testifies and they don't file the motion.

12   THE COURT: Yeah, that's fair. Why don't we just

13 wait and see what it is.

14   But once I get it, I'm going to ask you at that point

15 how much time do you need to respond, because I'm going to

16 want to hear from both sides, obviously.

17   MR. MARKETOS: Yes. Your Honor, I'll be frank. It's

18 an issue that's -- well, it's -- I think this is just an

19 effort to get Your Honor focused on something that's not an

20 issue, just similar to the whole DDMAC direct-to-consumer

21 issue, and I think -- I don't want us to have to spend a lot

22 of time responding to what we believe to be is just a

23 manufactured issue directed at the expert so -- because they

24 don't want the damages testimony to come in.

25   I think -- I think what I'll have to do is take a look

United States District Court
District of New Jersey

 1   at it. They're talking about one assumption that experts

 2   make, and he'll be able to attest to it today. We'll see if

 3   they maintain this issue after the fact, and then I guess I

 4   would, you know, want some time to respond, maybe, but I'm not

 5   going to take -- I hope not to have to take ourselves off

 6   track with respect to trial because they filed a mid-trial

 7   motion to strike an expert.

 8   THE COURT: All right. I hear you. Look, I'm not

 9   going to prevent Janssen -- I mean, we did talk about this,

10   and I said that I would allow this to be revisited if

11   something occurs during the testimony. So here's how I'll

12   leave it.

13   The testimony is going to come out today. You guys

14   will file something by tonight or tomorrow. Once we see what

15   it is, I'll come to you, Mr. Marketos, and say, Do you want to

16   respond verbally? Do you want to respond in writing? However

17   you want to respond, my point is I'm going to give you the

18   right to respond. If you're saying, Judge, I don't want to

19   have to put pen to paper on this. I think this is something

20   we can address evenly orally, I'm not going to prevent you

21   from doing that as well. I just don't want to take that right

22   away --

23   MR. MARKETOS: I understand.

24   THE COURT: -- if they put pen to paper that you

25   should have the ability to do the same in opposition.

United States District Court
District of New Jersey

1   MR. MARKETOS: Thank you, Your Honor.

2   THE COURT: So why don't we wait and see how this

3   plays out. Again, you're right. I don't know if Janssen will

4   file or not. If you do, though, it's either tonight or

5   tomorrow because I have to at least give an opportunity to

6   Relators, and I need some time to resolve the issue this week.

7   Because next week I don't know how -- when we only have

8   part of next week before this case is getting to the jury. So

9   I don't want to leave these issues outstanding until next

10   week. These issues should be resolved, I think, this week,

11   which is fair to the parties and also keeps us on schedule.

12   So what else? Anything other than that, Mr. Wyatt?

13   MR. WYATT: Nope. Thank you, Your Honor.

14   THE COURT: All right. And I don't anticipate any

15   other motions coming from Janssen. This is the last witness

16   that Relators are calling, correct?

17   MR. WYATT: We don't anticipate any others at this

18   time either, Judge.

19   THE COURT: All right.

20   And, Mr. Marketos, right now you don't anticipate

21   anything more from you, but we have to wait and see when

22   Janssen starts presenting their defense.

23   MR. MARKETOS: Yes, Your Honor. That's right.

24   THE COURT: Okay. What else, folks? Anything else

25   we need to chat about this morning?

United States District Court
District of New Jersey

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 1              MR. MARKETOS:  We're just ready to go, Your Honor.

 2              THE COURT:  All right.  And Ms. Brown, Mr. Wyatt,

 3   same thing?

 4              MS. BROWN:  No.  Thank you, Your Honor.

 5              THE COURT:  All right.  Well, we've got another --

 6   well, no, we should be going, shouldn't we?  What time are the

 7   jury going to be ready, 9?  We've got another 15 minutes.

 8         So why don't we be in recess for 15 minutes.  You all

 9   do what you need to do, and we'll make sure the jury is here,

10   and then we'll begin with the last witness and go from there.

11         We're in recess.  Everybody can remain seated.

12              MR. MARKETOS:  Thank you, Your Honor.

13              MR. WYATT:  Thank you, Your Honor.

14              MS. BROWN:  Thank you, Your Honor.

15         (A short recess occurred.)

16              THE DEPUTY COURT CLERK:  Please remain seated.

17              THE COURT:  Remind me, Mr. Marketos.  Did we already

18   call this witness, or are we calling him now this morning?

19              MR. MARKETOS:  No, Your Honor.  This is the intro.

20              THE COURT:  Got it.  Okay.

21           So let's get the jurors.

22           (Jury enters the courtroom.)

23              THE DEPUTY COURT CLERK:  All rise.

24              THE COURT:  All right.  Folks, everybody have a seat.

25   Members of the jury, welcome.  I hope you had a wonder
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United States District Court
District of New Jersey

1   weekend.

2   We're going to continue with the Relators' case. We

3   have, I believe, one witness left that's going to be called

4   today, then we'll be transferring over to Janssen's case with

5   one caveat; that Ms. Kaucher, who earlier testified, may be

6   returning back for the Relators' case at a later date during

7   the trial for the redirect examination.

8   So with that, Mr. Marketos, you ready to call that next

9   witness?

10   MR. MARKETOS: Yes, Your Honor. Thank you.

11   Good morning.

12   Your Honor, Relators call Professor Israel Shaked.

13   THE COURT: All right. Thank you.

14   (**Professor Israel Shaked**, HAVING BEEN DULY SWORN/AFFIRMED,

15   TESTIFIED AS FOLLOWS:)

16   THE DEPUTY COURT CLERK: Please state your name and

17   the spelling of your last name for the record.

18   THE WITNESS: Israel Shaked. Sorry.

19   THE COURT: I'm sorry. And the spelling of your last

20   name?

21   THE WITNESS: S-H-A-K-E-D.

22   THE COURT: All right. Mr. Marketos, whenever you're

23   ready to proceed, you may.

24   MR. MARKETOS: Thank you, Your Honor.

25   (DIRECT EXAMINATION BY MR. MARKETOS:)

United States District Court
District of New Jersey

1 Q. Good morning, Professor.

2 A. Good morning.

3 Q. Would you introduce yourself to the members of the jury,

4 please, sir?

5 A. Yes. My name is Israel Shaked.

6 Q. And where are you a professor?

7 A. Boston University.

8 Q. Sir, I'm going to ask you a few questions today, and

9 we're going to try to get the microphone situated so we can

10 both hear you and also not hear you breathing.

11   So it's going to be a challenge. So if you just try to

12 back away a little bit, Professor. Thank you so much.

13   Professor, are you providing testimony to the members

14 of the jury today on statistics and an analysis of behavior of

15 prescribers associated with Janssen' marketing?

16 A. Yes, that's the purpose, basically.

17 Q. And are you also going to present the members of the jury

18 with an economical analysis of the damages that the U.S.

19 Government and Government payors suffered as a result of

20 Janssen's off-label marketing and kickbacks?

21 A. Yes. This will come to at the end.

22 Q. Thank you, sir.

23   I'd like to just briefly discuss your credentials.

24   Professor, do you have a master's in business

25 administration?

United States District Court
District of New Jersey

1 A.   Yes.

2 Q.   And how about -- are you a Ph.D. from Harvard Business

3 School?

4 A.   Yes.   Doctor in business administration.

5 Q.   And how long have you been teaching as a professor at

6 Boston University?

7 A.   Many years.   43 and a half years.

8 Q.   What do you teach at Boston University?

9 A.   I teach -- I taught finances, capital market,

10 quantitative method for financial analysis.   43 years, I

11 taught many, many different classes.   Yeah.

12 Q.   And I'm going to -- I'm going to stop for a moment and go

13 back to your bachelor's degree.   Okay.

14   You have a college degree, a bachelor's degree in

15 economics and statistics as well.

16   Is that right?

17 A.   Yeah.   One BA in economics and a separate BA in

18 statistics.

19 Q.   Okay.

20   One bachelor's in economics, one bachelor's in

21 statistics.

22   And when you were in college, did you teach other

23 students?

24 A.   Yeah.   I was -- I was very active on teaching classes.

25 Q.   When you were pursuing your master's in business

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 1  administration, did you also teach other students?

 2  A.   Yes.

 3  Q.   And, sir, did you work while you were pursuing your

 4  master's in business administration?

 5  A.   Yes.  Actually, I had a full-time job at that time.

 6  Q.   You had a full-time job while you were pursuing your MBA?

 7  A.   Yes.  That's correct.

 8  Q.   Was that with Koor Chemicals?

 9  A.   This -- no.  The first one was with -- Koor is the second

10  job that I got.

11  Q.   Okay, sir.

12        Did you ever work for a synthetic drug manufacturer

13  that went by the name Koor?

14  A.   Koor -- Koor Chemicals, they had several companies, and

15  one of them that I was a liaison for the company was a

16  pharmaceutical company.

17  Q.   And while you were pursuing your MBA or after you

18  received your MBA, did you begin working for that company in

19  operational and financial strategy?

20  A.   Correct.

21  Q.   And while you were at Harvard Business School, can you

22  tell us -- did you start working at Boston University as an

23  assistant professor while you were pursuing your doctorate?

24  A.   Yes, I started at BU 1978 and got my doctorate in 1980.

25  So the last two years I was full-time faculty at BU and at
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 1 Harvard, yes.

 2 Q.   Okay.

 3   So you were pursuing your doctorate at Harvard while

 4 you were teaching at Boston University?

 5 A.   Yeah, to survive economically.

 6 Q.   Did you -- did you teach mostly finance and corporate

 7 finance and statistics while -- to students at Boston

 8 University?

 9 A.   Mostly financial analysis, including quantitative method,

10 which is analogy to statistics.

11 Q.   And eventually did you become an assistant professor at

12 Boston University full time?

13 A.   Yes. Assistant and then associate and then full

14 professor. That's different stages.

15 Q.   Okay, sir.

16   And did you teach other teachers? That is, did you

17 teach other professors how to teach?

18 A.   Yeah. For about 15 years I was a teaching master of the

19 school, teaching professors how not to put students to sleep

20 and also teaching doctoral students that are expected to be

21 professors. This was my responsibility for approximately

22 15 years.

23 Q.   Thank you, Professor.

24   And did you obtain full-time tenure at Boston

25 University?

United States District Court
District of New Jersey

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 1  A.   Oh, yes.  Of course.

 2  Q.   Was that in 1984?

 3  A.   Mid-80's, yeah, '84, '85.  I can't remember exactly.

 4  Q.   And, sir, did you ultimately become a professor emeritus

 5  at Boston University?

 6  A.   Yeah.  That -- correct.

 7  Q.   And was that in January of 2022?

 8  A.   Correct.  Just January '22, correct.

 9  Q.   And so approximately 40-plus years as a professor at

10  Boston University.

11       Is that right?

12  A.   That's right.

13  Q.   And, sir, while you were working at Boston University as

14  a professor, while you were teaching students and other -- and

15  other professors, did you also perform any services in

16  consulting?

17  A.   Yes.

18  Q.   And tell us a little bit about that.  Do you have a

19  company that's called the Michel-Shaked Group?

20  A.   That's correct.

21  Q.   What type of consulting services does that company

22  provide?

23  A.   We have three lines of business mostly.  We started in

24  the 80s and in the 80s lost a few -- a little bit -- all those

25  in their 20 or 30 know that there was also mergers and
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 1  acquisitions, leverage buyouts, companies who are buying other

 2  companies.

 3       So at that time most of our advice was to advise

 4  companies about mergers and acquisitions, including startups,

 5  and how to defend yourself from a large company taking over

 6  your business.

 7  Q.   Okay.

 8       So you're talking about the 1980s when there are lots

 9  of mergers and acquisitions.  You would advise companies on

10  how to defend themselves if somebody was trying to acquire

11  them?

12  A.   This was one of our main lines.  That's the reason that

13  we -- we started basically advising, and then companies that

14  we worked with were targets of takeovers, so we advise them,

15  and we became quite specialized in that in the 80s.

16  Q.   Understood, sir.

17       And did you actually -- did you publish any books on

18  that topic?

19  A.   Yeah, the very colorful cover.  The name is "Takeover

20  Madness:  Corporate America Fights Back."

21       This is the first book that I coauthored with my

22  colleague, and it's basically advising companies how to defend

23  themselves from hostile takeovers.

24  Q.   Just a quick anecdote, Professor.

25       That book -- there is a movie that was out when I was a
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1   kid called "The Secret of My Success."

2   A.   Okay.

3   Q.   I'm sorry to ask you that. Was that book featured in

4   that movie?

5   A.   Not that -- yeah, Michael J. Fox, he was taking over the

6   companies that -- he supposedly was starting in the mailroom

7   and went up, and he had only one thing on his desk, our book.

8   I have no idea why and how, but this was there.

9   Q.   Okay.

10   You also wrote a book called "Complete Guide to a

11 Successful Leveraged Buyout."

12   Do you recall that?

13 A.   That's correct.

14 Q.   And "Finance and Accounting For Lawyers"?

15 A.   Finance -- that's a challenge, but I tried to teach

16 lawyers.

17 Q.   Yeah, thank you. I never read it.

18   How about "A Practical Guide to Bankruptcy Valuation"?

19 Did you write that as well?

20 A.   Yes.

21 Q.   All right.

22   Thank you, Professor.

23   How about with respect to prior litigations? Have you

24 had an opportunity to testify before Congress?

25 A.   That's correct.

United States District Court
District of New Jersey

1 Q.   And the House Ways and Means Committee on behalf of and

2 against the Internal Revenue Service?

3 A.   That's separate, right? I worked -- testified in

4 Congress, and I worked for and against Internal Revenue

5 Service; that's right.

6 Q.   What type of -- just very quickly: What type of

7 testimony did you provide before Congress?

8 A.   Congress -- the idea is Congress wanted to exclude the

9 interest rate -- interest deduction, so if you buy a company,

10 you cannot deduct the cost of that -- the interest.

11   And they wanted to solicit opinions, and I was one of

12 the few that testified before Congress on behalf of the

13 companies, not to -- you know, not to exclude the interest.

14 It didn't make sense to me.

15 Q.   And have you been asked to provide consulting services to

16 the U.S. Department of Justice before?

17 A.   Yes.

18 Q.   All right, sir.

19   And what about with respect to the FDIC? Have you

20 consulted for and analyzed issues for the FDIC, the Federal

21 Deposit Insurance Corporation?

22 A.   Yes. When you walk into the bank, there is a sign,

23 Member of the FDIC, and basically the FDIC has to charge the

24 bank because FDIC takes a risk, and I develop a methodology

25 that FDIC actually adopted, how much to charge the bank for

 1   assuming this insurance, so it gives them this insurance.

 2   Q.   Thank you, sir.

 3   Have you also consulted on matters relating to

 4   pharmaceutical companies before?

 5   A.   That's correct.

 6   Q.   And how about with respect to pharmacies themselves?

 7   A.   I -- I did work for cases involving pharmacies.

 8   Q.   You've been involved in some prior shareholder litigation

 9   as well.

10   Were you involved in what some of us may remember --

11   were you involved in the Enron litigation during Enron's

12   bankruptcy?

13   A.   Yes.

14   Q.   And what types of information did you analyze on behalf

15   of shareholders after Enron went bankrupt and collapsed?

16   A.   I know that Enron sounds very old name for the youngest

17   among you, but the main idea about Enron -- they were allotted

18   these billions of dollars of debt that nobody knew. However,

19   the banks kept financing them, so I testified on behalf of the

20   shareholders against Goldman Sachs and J.P. Morgan, a large

21   number of -- heavy, deep pockets companies that finance Enron

22   and were responsible for basically the -- were involved with

23   the fraud indirectly.

24   So this was allowed just -- award to shareholders at

25   that time, 6.2 billion or 7.2. I can't remember.

United States District Court
District of New Jersey

1 Q. Professor Shaked, when you provide your consulting

2 services, do you provide or leverage your background in

3 statistics and economics in order to provide your opinions?

4 A. Depends on the case. Virtually the majority of my

5 academic -- pure academic articles always -- almost always

6 have some statistics in it.

7   That's called publish or perish. You have to stay --

8 in academia you have to use the most advanced technologies.

9 So there are lots of statistics there. And some of them,

10 some of the work that they do, like the FDIC, it's a very

11 advanced also methodology, but not always, but quite many of

12 them.

13 Q. Let's take a look, and let's turn your attention to the

14 scope of your engagement in this case. All right, sir?

15   What is it that you were asked to analyze and provide

16 an opinion on as an expert in statistics and economical

17 analysis, Professor?

18 A. There are two layers that are really important here. The

19 first one has to do with the speakers. And you can see I both

20 analyze and opine on A, the total compensation that they

21 spend.

22   That's not only the speakers, but I like to know --

23 also and I analyzed the data -- the relationship between the

24 compensation paid to the speakers and how much they prescribe

25 to see whether there is any relationship between the two.

1 My -- there is no relationship. I didn't have any prior

2 opinion. I really tell you, it could be anywhere.

3   And the other one is to do with off-label marketing.

4 So off-label marketing is basically to know how many of the

5 people that are influenced -- and I really define it in a

6 couple minutes, with -- were in relationship with Janssen, in

7 either way, one of the two, three ways, and how much they

8 wrote off label.

9   Now, given that, the total damages were determined --

10 or told me to do this calculation, which means I'm not here

11 for any legal or medical opinion. I never prescribed not even

12 a Tylenol. Okay?

13   So I don't know anything about that, but I was told to

14 take all the payments -- all the payments by the U.S.

15 Government for claims submitted by Janssen that were written

16 by the speakers, and separately, the claims that were related

17 to the off-label prescriptions.

18 Q.   Thank you, Professor Shaked. Let me -- let me summarize,

19 if I can.

20   There's a -- there's a section of your analysis that

21 first looks at total compensation paid to doctors that were

22 serving on these promotional speakers' bureaus.

23   Correct?

24 A.   Correct.

25 Q.   And then there's two relationships that you were studying

1   statistically, as I understand it.

2   The first relationship is the amount of money that was

3   paid to those doctors and how much they subsequently wrote in

4   terms of prescriptions for Prezista and Intelence.

5   A.   Correct.

6   Q.   And then you analyzed the relationship between Janssen's

7   off-label marketing efforts, the efforts of the sales force,

8   and doctors' subsequent levels of prescribing those drugs off

9   label.

10   Is that right?

11 A.   Absolutely.

12 Q.   And before I get into your Janssen analysis, what -- what

13 amount of data -- in order to compare the relationship between

14 Janssen's off-label marketing contacts with doctors and

15 prescribers and their subsequent prescription rates, their

16 rates of prescribing off label, what datasets did you analyze?

17 A.   As I say, I see Ian Dew was the calculation when he

18 talked about the data.

19 Q.   Yes.

20 A.   Frankly, no consulting firm of our size or any size can

21 handle that unless they specialize in large data analyses.

22 There were hundreds of millions of data points. That's what

23 we started with, 360 million.

24   I got already screened by many Excel saying, This is

25 all the speakers, this is all the amounts, this is all the

1 prescription. And I asked him, Find A, B, C, D, so the amount

2 of data is way before -- at most, so it's more than any one of

3 the computers like mine can handle.

4 Q.   Okay.

5 A.   So I rely on retrieving information on Ian Dew.

6 Q.   Okay.

7   So there's data from the federal government and the

8 government payors?

9 A.   Right.

10 Q.   Was there data from Janssen?

11 A.   It was data from Janssen, yes. There was data from

12 Janssen about number of calls and the -- who did they call,

13 you know, and the speakers and how much they got paid.

14   Janssen provided the information that at least I was

15 quite -- you know, it was useful for me, the information

16 provided by Janssen.

17 Q.   Okay.

18   There was data provided by Janssen. And then is there

19 data associated with the physicians' prescription rates for

20 off-label prescriptions that you were able to obtain from

21 Ian Dew from the government payors?

22 A.   That's correct.

23 Q.   And then finally, sir, there's a total amount of damages

24 at the bottom that is associated with unlawful kickbacks paid

25 to doctors.

1   Is that an amount that you're going to tabulate and

2   explain to the jury, the amount that the government ended up

3   paying for those prescriptions?

4   A.   Absolutely, yes.

5   Q.   And how about with respect to the amount that federal

6   government payors paid for off-label marketing of Prezista and

7   Intelence?

8   A.   Yeah. I did that one -- two separate ones. I have two

9   separate, one for each line.

10   Q.   You understand that one of those amounts is associated

11   with the claim for the violations of the Anti-Kickback Statute

12   and the other associated with the False Claims Act for

13   off-label marketing.

14   Is that right?

15   A.   That's right.

16   Q.   Well, let's get into the background, if we could, sir.

17   I want to skip over some of the terms that we had in

18   there because I think the members of the jury after this long

19   understand treatment naive and treatment experienced.

20   Let's just -- let's see if we can just move this along.

21   What was your understanding of the issue with respect

22   to the adverse reactions or the serious adverse reactions

23   relating to Prezista?

24   A.   I think that the focus and the primary issue surrounding

25   Prezista was a lipid. And as I said, the adverse reaction

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 1  indicated that it's not really asked to be given voluntarily

 2  or excessively or whatever.  I don't know exactly the

 3  language, but it should not be given to somebody with

 4  treatment naive, only to treatment experienced.

 5  Q.   Okay, sir.

 6  A.   And the other one has to do with the lipid, as I say,

 7  that if you know that somebody is on lipid, my understanding

 8  is -- that's what I was advised.  It's not my opinion, but I

 9  talk to Dr. Glatt -- not talked.

10       I communicated to Dr. Glatt and through the counsel

11  with Dr. Glatt and somebody else, and they told me or advised

12  me to look -- that I should look for some indication in the

13  past related to lipids.

14  Q.   All right, sir.

15       And so Dr. Aaron Glatt came and provided testimony to

16  the members of the jury.  Were you present for Dr. Glatt's

17  testimony?  Were you present in court when Dr. Glatt

18  testified?

19  A.   Correct.  I was here, yes.

20  Q.   And Dr. Glatt gave opinions with respect to the lipid

21  adverse reactions for this drug.

22       Do you recall that?

23  A.   Yes.

24  Q.   All right.

25       Now, did Prezista -- during the time period from 2006
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United States District Court
District of New Jersey

1   to 2014, did Janssen receive money for Prezista prescriptions

2   that were ultimately reimbursed by the government payors?

3   A.   Yes.

4   Q.   And what was the total amount of government

5   reimbursements for Prezista prescriptions during that time

6   period, 2006 to 2014?

7   A.   The total I obtained indicated it's about $2.35 billion.

8   Q.   Just for Prezista?

9   A.   Just for Prezista; that's correct.

10   Q.   Now, sir, what about -- what did you look at with respect

11   to Prezista when it went on -- went out into the market

12   beginning in 2006?

13   How did Janssen and Prezista perform over time compared

14   to the competitors that were in existence at the time?

15   A.   Prezista did very well. You can see here this is market

16   shares. It's not sales, but it's what you call market share.

17   It means the percentage of the market which is Prezista, and

18   if you take a look, Prezista 2011 and 2014 went up by about --

19   from 17 to 25.6, by about 8.6 percent.

20   So the market share did go up. Now, by the way, one

21   thing that might be misleading sometimes, people see that the

22   other two, which are a competitor, are declining. It doesn't

23   mean that lost sales. It means that they grew less than

24   Prezista.

25   If you are going faster than your competitor, it might

United States District Court
District of New Jersey

 1 | show that the competitor's market share declined, but it might

 2 | be sales still went up. But still they did better than the

 3 | primary two competitors which are listed here, which are

 4 | Reyataz and Kaletra.

 5 | Q.   And if we take a look at -- let's turn your attention for

 6 | the time being to Intelence. All right. How about with

 7 | respect to Intelence? Was it your understanding, Professor,

 8 | that Intelence was or was not approved for treatment-naive

 9 | patients?

10 | A.   Was never approved.

11 | Q.   And how about with respect to once-daily dosing?

12 | A.   Also, similar -- identically, not similarly. It was

13 | never approved for giving it once a day and not approved for

14 | treatment naive.

15 | Q.   What was -- can you tell the members of the jury: What

16 | were the total government reimbursements for Intelence during

17 | the time period from 2008 when it went onto the market and

18 | 2014?

19 | A.   Nearly 600 million, 597.6.

20 | Q.   Now, let's turn your attention, Professor, to your

21 | analysis of the two separate issues that you calculated

22 | damages for, kickbacks and off-label marketing.

23 | Okay, sir?

24 | A.   Okay.

25 | Q.   Let's talk about what you have defined for the purposes

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 1  of your analysis as an influenced physician or an influenced

 2  prescriber.

 3       Okay, sir?

 4  A.  Yes.

 5  Q.  When you're talking about an influenced prescriber for

 6  the purposes of framing your analysis, was the first one

 7  speaking -- a doctor speaking at a speaking event?

 8  A.  The left side indicated by the number 1, one way

 9  somebody's considered to be influenced.  You also --

10  influencing other people is speaking at the speaking event.

11  Q.  And how about the attendees at a speaking event?

12       And let me just, for the time being -- for instance,

13  those would be doctors who were in the audience at a

14  restaurant over the course of several thousand speaking

15  events.

16       Is that fair?

17  A.  That's correct.  I added some good restaurants, by the

18  way.

19  Q.  Yes.  And -- and then number 3, receiving Janssen's

20  marketing from a sales representative, and this is important.

21       Did you also consider Janssen's actual marketing

22  efforts, what they call call details or doctor visits, to be

23  an influence on doctors who were hearing those messages?

24  A.  And as we see later, there were about 620,000 calls given

25  over this period to doctors.
```

1 Q.   Okay.

2   And let me -- let me stop there for a second.

3   That's from Janssen's data on the number of times one

4 of the 100-plus sales representatives called upon, visited a

5 doctor or a prescriber.

6   Is that right?

7 A.   That's correct.

8 Q.   And during this time period from 2006 to 2014, that

9 database has 620,000 contacts between the Janssen sales

10 representatives and the physicians.

11   Is that right?

12 A.   Absolutely, yes.

13 Q.   All right.

14   So with those three -- the framework of those three

15 separate forms of contact or influence, did you begin your

16 analysis?

17 A.   That's correct. That's -- that's really -- frames

18 influenced, defined it.

19 Q.   And, sir, let's just talk about very quickly definitions.

20   The lipids claim, did you define that as all Prezista

21 prescriptions that were written for patients who had any --

22 who were already on any lipid-regulating medication or had a

23 lipid-related diagnosis before they were prescribed Prezista?

24 A.   My only correction to your statement, which I shouldn't

25 do maybe, is not that I define it. I rely on the definition

United States District Court
District of New Jersey

1   by the doctor and few other sources.

2   I am not here for any legal reason -- medical reason,

3   so I was provided with information that anybody who has any

4   lipid-related regulating medicine or diagnosis should be

5   considered as risk or -- not taking Prezista.

6   Q.   Okay, sir.

7   So, in other words, were you provided this information

8   by Dr. Glatt for a patient who received any lipid-related

9   medication or any lipid-related diagnosis?

10 A.   No --

11 Q.   Was that his parameters?

12 A.   This was his parameters as provided to the counsel, and

13 they provided to me.

14 Q.   All right, sir.

15   And how about with respect to a treatment-naive claim?

16 Did you consider that to be a Prezista prescription that was

17 written for patients who were outside of the label for

18 Prezista, that is, those who were not taking any

19 antiretroviral medication?

20 A.   What I did -- my data was only -- not only but all the

21 way in 2006, so step one, I went all the way back to 2006, and

22 I ask Ian -- that was the other guy -- to find whether there

23 is in the database any ARV.

24 Q.   ARV? I'm sorry?

25 A.   ARV is any medication given to HIV -- HIV patient.

1   Q.   Antiretroviral?

2   A.   Antiretroviral, correct.

3   Q.   Thank you.

4   A.   And in addition, on the safe side, I went also 90 days

5   after the first time that they got Prezista, I mean, in a

6   patient to see that maybe I missed something and the ARV is in

7   this period.

8   So I went 90 days after the first day and as many use

9   as needed before that.

10 Q.   All right.

11   Now, let's turn your attention to the Intelence

12 off-label claims.

13   For Intelence treatment-naive claims, did you look to

14 see prescriptions that were written for Intelence for

15 treatment-naive patients, that is, those who were previously

16 not taking an antiretroviral medication?

17 A.   Exactly the same methodology as for Prezista.

18 Q.   Now, how about with respect to Intelence once-daily

19 dosage? Did you just identify -- were you able to obtain data

20 from Ian Dew to identify prescriptions written for Intelence

21 once-daily dosing?

22 A.   Yes. Basically, it was not in the government database,

23 but we were -- went to the pharmacies, and we found -- we

24 found about 219,000 off Walgreens, and another 40-plus

25 thousands off of another one, and 38,000 of BioScrips, so

United States District Court
District of New Jersey

 1   about 300,000 data point.

 2   Now, I was asked the position whether I feel that it's

 3   representative. Very few times in my life I had the luxury of

 4   having 300,000 numbers as a basis for my opinion.

 5   That's -- that's plenty.

 6   Q.   And that's information that Mr. Dew was able to obtain

 7   from pharmacies to use as a statistical basis for once-daily

 8   dosing for Intelence; is that correct?

 9   A.   Correct. Correct.

10   Q.   Now, let's talk about the separate methodologies for

11   analyzing damages.

12   You've got, on the kickback side, Janssen providing

13   kickbacks to speakers and damages associated with that. Can

14   you explain the damages relating to all of the speakers'

15   prescriptions for Prezista and Intelence that were written

16   after their first speech, their first paid speech?

17   A.   Right. That was relatively simple.

18   I just went to the first day that the person did

19   deliver a speech, and I went after that to find all the

20   prescription that this person wrote. This was part of the

21   kickback, what the lawyers call "kickback damages."

22   Q.   And, sir, were you provided a legal framework for that as

23   well? Were you made aware of the way that the law provides

24   for kickback damages to be awarded?

25   A.   Yeah. I just was in another case a few months ago --

United States District Court
District of New Jersey

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 1              MS. BROWN:  Objection, Your Honor.

 2              THE WITNESS:  -- against other company and --

 3              THE COURT:  Sustained.

 4              MR. MARKETOS:  I'll rephrase.  I'm sorry.

 5              MS. BROWN:  Can we strike that, Your Honor, please?

 6              THE COURT:  Yeah.  Just not to consider the other

 7  matter that you're testifying about.

 8              THE WITNESS:  I appreciate it.  Thanks, Your Honor.

 9  BY MR. MARKETOS:

10  Q.   Yeah.  Sorry, Professor.

11         Were you made aware of -- in order to perform your

12  analysis, were you made aware of the way that the law provides

13  for kickbacks to be calculated?

14              MS. BROWN:  Same objection, Your Honor.

15              THE COURT:  Let me see you folks at sidebar.

16              (Sidebar begins at 9:32 a.m.)

17              THE COURT:  Sorry.  The objection is -- what's the

18  objection?

19              MS. BROWN:  To the law, Your Honor.  If he wants to

20  say, this was the assumption that you made or that you, you

21  know, calculated your damages on, that's fine.  But the Court

22  is going to instruct on what the law is, and counsel's

23  questions are saying, were you made aware of the law.

24              THE COURT:  As opposed to were you given some

25  guidance on the law, like assumptions based on the law from
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United States District Court
District of New Jersey

1   counsel.

2   It's really just how you're phrasing it. You can get

3   your question out, Mr. Marketos. You can't make a definitive

4   that he was told what -- that the law he was told is accurate,

5   right? In other words, you can say, Were you given some

6   guidance on the law for purposes of your assumptions for your

7   analysis?

8   MS. BROWN: But -- and even that, Your Honor, I mean,

9   I would object to anything referencing "the law." I mean,

10 were you told to assume this was the law or were you told to

11 assume this. But the guidance on the --

12   MR. MARKETOS: I can do that.

13   THE COURT: I think that's fair.

14   (Sidebar was concluded at 9:33 a.m.)

15   (Open court.)

16 BY MR. MARKETOS:

17 Q.   Professor Shaked, with respect to kickback calculations,

18 were you instructed to assume certain methods of calculation

19 based upon the law associated with kickbacks?

20 A.   Yes.

21 Q.   All right, sir.

22   And then for off-label marketing, Janssen providing

23 off-label marketing to doctors, were there damages that were

24 calculated based upon all of the influenced physicians who

25 first wrote a prescription for Prezista and Intelence

United States District Court
District of New Jersey

1 off-label?

2 A.   Right.   The word used is "initiated," which means the

3 first prescriber, as well as "attributed."   Attributed means

4 if an influence started giving off-label and another doctor

5 adopted it as a second one, it's part of the damages.

6 Q.   And were you trying to capture, Professor, with respect

7 to the off-label marketing, were you trying to capture all

8 off-label prescriptions that were written for Prezista and

9 Intelence, or only those that were first written by one of the

10 physicians who was influenced by Janssen's marketing?

11 A.   I see that your second half is correct.   It's only by

12 influence.

13   Moreover, if a noninfluence and an influence adopted an

14 off-label, it's not in my damages.

15 Q.   Okay, sir?

16   So just to be clear, if a doctor who had never received

17 any contact from Janssen, who had never received a marketing

18 message, who had never attended a speaking event or been paid

19 to speak, had written a prescription for Prezista off-label,

20 is that part of your damages calculations or not?

21 A.   Absolutely not.

22 Q.   Okay.

23   If we take a look now -- and we'll focus on the

24 anti-kickback analyses for speakers compensation and

25 subsequent prescriptions.

1   Okay?

2   A.   Yeah.

3   Q.   Please let the members of the jury know what information

4   you obtained first.

5   And, sir, first you're going to look at their behavior

6   before you actually analyze the amount of damages to

7   government payors.

8   Is that right?

9   A.   Yeah. Damages comes last.

10 Q.   Okay.

11   So in order to look at the behavior, the relationship

12 between speaker payments and their prescribing behavior, did

13 you first identify the total amount of money that Janssen paid

14 to speak -- speaking doctors on its Promotional Speaker

15 Bureau?

16 A.   Yes.

17 Q.   And if we take a look here, sir, for the years 2006

18 through 2014, were there checks for honoraria that -- checks

19 written to speakers for speaking on the Promotional Speaker

20 Bureau?

21 A.   Yes. That's -- that's called honoraria.

22 Q.   Who called it honoraria? I'm sorry.

23 A.   It's expected to be a symbolic amount. I'm not here to

24 opine on that.

25 Q.   Okay.

United States District Court
District of New Jersey

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 1         And that's over $14 million just straight to doctors.

 2         Is that right?

 3  A.   That's correct.

 4  Q.   And then there's a total amount that was reimbursed to

 5  these doctors for -- the check for speaking and training fees

 6  and expenses and consulting fees and consulting expenses, and

 7  that total is more than $17 million.

 8         Do you see that?

 9  A.   That's correct.

10  Q.   Now, if you could, sir, explain how that total amount of

11  compensation that Janssen was paying to doctors is compared to

12  the total amount of prescriptions that those doctors wrote for

13  Prezista and Intelence that Janssen received reimbursement for

14  from government payors.

15  A.   As the title say, that this is a speaker compensation

16  versus speaker Prezista and Intelence RX.  That's the one in

17  the orange with the color here.

18         Now, the reason I just look at this, that's still not

19  proof of anything.  I don't see the proof for behavior or so,

20  but what's really interesting is is that you have 321

21  speakers, and in this period, just in this period, up to 2014,

22  the average is over a million per speaker.  If you divide 327

23  by 321, you get about 1.02.  It's approximately one million

24  per speaker.

25         This is a amount of prescription generated by the
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 1  speakers.
 2  Q.   So on the right hand -- so on the left-hand side, we have
 3  an outlay Janssen paying to speakers.
 4       Is that right?
 5  A.   That's correct.
 6  Q.   And on the right-hand side, you have an amount that
 7  Janssen ultimately received with respect to the prescriptions
 8  that those doctors wrote for Prezista and Intelence.
 9       Is that correct?
10  A.   And paid by the government.
11  Q.   $327 million?
12  A.   That's correct.
13  Q.   So over -- why do you say over $327.2 million of
14  speakers' prescriptions for Intelence and Prezista were
15  reimbursed by the government?
16  A.   As I said more than once, I'm not here for any legal
17  reason.  But I was advised -- I don't know exactly the
18  background -- to start calculating the damages in 2014.
19       However, there is no doubt that many of the thousand
20  patients keep getting the same prescription after 2014.  So if
21  somebody would go over 2014, definitely you will have many
22  more -- many more amounts here.
23  Q.   So --
24  A.   Another -- another reason is -- another reason is based
25  on Ian, who was the data guy.
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1   Q.   Ian Dew?

2   A.   Ian Dew, sorry.

3   We get -- we did get Medicaid, access to Medicaid

4   database. About out of 1.1 million claims of -- so of

5   Medicaid, about 392,000 were not really very, very clear.

6   Okay? So we don't have exact amount for this one.

7   So the Medicaid is only two-third of the amount. I

8   don't know the rest of it. So we decided not to use anything

9   that we don't have data for.

10   So the 327 is only up to 2014, and only Medicare and

11   Medicaid up to the limit of data availability.

12   Q.   Thank you, Professor.

13   So if you had had access to all of the data from

14   Medicaid as opposed to two-thirds of it and you were to

15   calculate all prescriptions for patients past 2014 written by

16   these doctors, would you have expected the amount of

17   government reimbursement that Janssen benefited from to be

18   significantly higher?

19   A.   A lot higher, because, as I said, Medicare, especially,

20   we have a shortcoming of data availability, so we left it out

21   when it was not clear. It's a large number of claims we left

22   on the table.

23   Q.   For the purposes of your analysis and your testimony to

24   the members of the jury, though, you're attesting to the lower

25   number of $327.2 million.

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 1          Is that right?
 2    A.    That's the reason I added the word "over."  But I am not
 3    going to opine or conclude on anything above 327.2.
 4    Q.    Thank you, Professor.
 5          Now, let's take a look at the speakers themselves and
 6    their levels of prescriptions of Prezista and Intelence.
 7          All right, sir?
 8    A.    Yes.
 9    Q.    Now, this slide, Professor, slide 24, you state that
10    "Speakers prescribed 11 percent of all Prezista and Intelence
11    prescriptions while accounting for only .31 percent of all
12    doctors who prescribed at least one antiretroviral drug during
13    the time period from 2006 until 2014."
14          Why did you look at that data?  Why did you analyze
15    those proportions?
16    A.    Yeah.  Before talking about compensation and anything, I
17    wanted to see the extent of prescription writing by the
18    speakers.
19          And you have to remember that, in 2006, '7, '8,
20    Prezista was still relatively new.  Also in 2008, '9, '10,
21    Intelence was relatively new.  So these speakers supposedly
22    are about 1 over 300 of the doctors -- you say all physicians,
23    and we talk about --
24    Q.    I apologize, Professor.
25          You said 1 over 300.
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United States District Court
District of New Jersey

1   Is that why you have .31 percent?

2   A.   Correct. Absolutely appreciate it. You know,

3   .31 percent, I right away, you know, translate in my head to 1

4   over 300. Because if 1 percent is 1 over 100, one-third of a

5   percent is 1 over 300.

6   And I went to all the doctors and did at least one ARV,

7   at least one HIV patient-related medicine. So that 1/30 --

8   1/300, so 1 over 300 of the doctors, and they prescribed 1 out

9   of every $9. 11 percent is 1 out of 9.

10   So still, I don't see any wrongdoing. But, to me, it

11   seems very, very -- I use the word disproportionate, like to

12   the liberty, which I rarely do, to say 1 over 300 writing 1

13   over 9, that's, to me, a little bit of a misbalance, unusual.

14   Q.   Okay.

15   So in terms of the 335 -- there are 335 doctors

16   speaking on the speaker bureau, and that amounts to .31

17   percent of all doctors in the nation that had prescribed an

18   antiretroviral drug.

19   Is that right?

20   A.   That's correct.

21   Q.   Yet, with respect to government reimbursements for

22   Prezista and Intelence, that group of speakers amounts to over

23   11 percent of all of the prescriptions for Prezista and

24   Intelence?

25   A.   Right. This is 1 out of every $9 for -- it was

1 prescribed by them. Sorry.

2 Q.   All right.

3   And is that just something that you've now displayed

4 graphically on this slide, sir?

5 A.   Right. It looks very unusual. As I say, that's not

6 proof of anything, but it implies that something very unusual

7 happens as you will see later when I have more data.

8 Q.   And you say at the bottom here that an average speaker, a

9 doctor on Janssen's Promotional Speaker Bureau, prescribed 36

10 times more Prezista and Intelence than an average nonspeaker.

11   Is that correct?

12 A.   That's correct.

13 Q.   How about an analysis? Did you perform an analysis of

14 the speakers' tendencies to prescribe Prezista compared to

15 non-speakers?

16 A.   When you take a look at this one page, there is no doubt,

17 absolutely no doubt, in my opinion, that speakers were more

18 likely than non-speakers to prescribe Prezista and Intelence.

19 There's no doubt about it.

20   On the left-hand side, we have something called the

21 median. On the right side, I wrote the average. I know that

22 we are not in the statisticals, but I like to maybe elaborate

23 how to read this information.

24 Q.   And let's do that, sir.

25   On the right-hand side, you've got an average. That's

1   just a mathematical calculation.

2   Is that correct?

3   A.   Summation and dividing, correct. It's simple. Average,

4   most people know. Most of us know.

5   Q.   Yes, sir.

6   But on the left-hand side, there's a median. Is that a

7   statistical analysis?

8   A.   That is a statistical measure, correct.

9   Q.   Thank you.

10   And what is the median a statistical measure of?

11   A.   If you want to know, for example, who is typical, say,

12   typical prescriber? Why do I use the median? I will give you

13   two very short examples.

14   One of them is if you have a neighborhood, which is

15   average neighborhood, and there is one Bill Gates in this

16   neighborhood, the average income in this neighborhood would be

17   very high. You can keep any neighborhood with his -- you

18   know, with his income. Keep in the sense of affect.

19   However, if you rank them and find the person in the

20   middle, that's the median. You rank them and find the person

21   in the median, the median would be very low.

22   Now, another example that I absolutely love, because I

23   love basketball, it's called the Michael Jordan fallacy. You

24   might want to know that the highest graduating income in 1986

25   from University of North Carolina was the department of

1 | geography. Don't try to get a geography degree. I tell you

2 | why. Because the department was small and one of the

3 | graduates was Michael Jordan.

4 | So everyone was making 22,000. So if you rank them,

5 | the middle is 22,000. But if you add them and calculate

6 | average, the average was $250,000.

7 | Q.   So Michael Jordan went to the NBA.

8 | A.   Michael Jordan -- maybe just promote the geography

9 | studies. Everyone say, if you can jump and run fast, you can

10 | make 250,000 if you're in geography.

11 | Q.   So -- so is that to eliminate the bias so that everybody

12 | doesn't run out and get a geography degree?

13 | A.   Yeah. The same thing is prescription. You really want

14 | to avoid outliers. You want to rank the people and find what

15 | the typical one, what the typical prescriber or typical

16 | geography person make with a degree and so on.

17 | Q.   Thank you, Professor.

18 | And when we're looking at this graph on the left, you

19 | see that the typical, the median non- -- the nonspeaker wrote

20 | 0.0 percent prescriptions of Prezista and Intelence.

21 | Do you see that?

22 | A.   Right.

23 | Q.   What does that mean?

24 | A.   The ratio is basically dividing. The ratio is you take

25 | number of -- number of Prezista and Intelence, Intelence that

United States District Court
District of New Jersey

1   somebody prescribed, and you divide it by all the ARV. Not

2   only Prezista and Intelence, also other one, because there are

3   many other ones competing.

4   Now -- so you do this ratio for every one of the

5   doctors, and you rank them. In this case, it's speakers. You

6   rank all the 300 of them and find how much is the middle.

7   Turn out that the middle one, which is a typical one, did not

8   even prescribe Prezista or Intelence. It's zero. You can see

9   the median here is 0.0 --

10   Q.   How --

11   A.   -- for non-speakers.

12   Q.   And how did that compare to the speakers themselves?

13   A.   Speakers of 10.2, which is significantly higher,

14   obviously. No doubt about it. I didn't apply any statistical

15   test to see whether the 10.2 is significantly -- statistically

16   significant different than zero. This would be a no-brainer.

17   Q.   A no-brainer.

18   Let's take a look at the next slide. Physicians who

19   prescribed -- is this just looking at what we just looked at

20   but the inverse? In other words, what was the typical -- tell

21   us about the percentage of doctors who prescribed no Prezista

22   or Intelence compared to the number -- or the percentage of

23   speakers --

24   A.   If you go --

25   Q.   I'm sorry. Sorry, just for the record.

United States District Court
District of New Jersey

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 1            -- the percentage of speakers who prescribed no

 2   Prezista or Intelence.

 3   A.   If you go back for a second, just to the previous one,

 4   like, you can see that it say the median is zero.  All that

 5   you know here is that at least 54,000 of them, they never

 6   prescribed Prezista or Intelence.  You don't know how many.  I

 7   know the median zero means the first 50-plus thousand don't.

 8        So now I go to the next slide, and I actually checked

 9   in the database how many of them are zero.  Turn out, it's

10   significantly more then 50.  77.2 percent of the non-speakers

11   did not prescribe either Intelence or Prezista.

12        Now, you can see -- sorry -- to go back to it.  Only

13   1.3 percent of the speakers did not prescribe.  1.3 out of 300

14   is 4 speakers out of 3-plus hundred, 320 -- or 321, I believe,

15   did not prescribe, while the typical one, which is a

16   nonspeaker, 77 percent never prescribed either Intelence or

17   Prezista.

18   Q.   Thank you, Professor.

19        And were you able to perform -- let's -- were you able

20   to perform a statistical analysis to eliminate the potential

21   that that ratio that we just looked at was the product of a

22   chance event?

23   A.   Yeah, I did.

24   Q.   And explain, if you would, sir, what a Z-Score test is.

25        And, Professor, I'll remind you that you teach people
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United States District Court
District of New Jersey

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 1   how to teach people how not to fall asleep.  So --

 2   A.   And at 9:45 in the morning is not the best time to teach

 3   people about the Z-Score, but I will try to do the best.

 4   Q.   Okay.  Thank you.

 5   A.   Okay.

 6        The idea is that we have a test -- if you have two

 7   averages -- if either median I forgot, because it's zero

 8   versus ten, I didn't test it.  I tested the averages.  The

 9   average here is 4.9 percent for nonspeaker versus 10.4.

10        So there is a test of averages.  You take a look at one

11   of them.  Where is the average and dispersion and all kind of

12   statistical characteristic, and for the speakers you take a

13   look, and basically you compare the averages, and there is

14   something called a Z-Score.

15        The Z-Score sounds intimidating, but it's no big deal.

16   It's a measure that, if it's above 1.65, the difference is

17   statistically significant.  If it's less than 1.65, you cannot

18   really claim that they are statistically different.

19        Now, the 21.48 is so high compared to the 1.65, the

20   chance or the probability that this is by chance is very, very

21   low.  In fact, 1 over 1 billion.  That, to give you the sense,

22   the New Jersey big multimillion lottery, state lottery, you

23   have a chance of 1 over 302 million.  I checked it.

24        So the chance that this is by not really -- sorry.  The

25   probabilities that this difference is chance is even smaller
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United States District Court
District of New Jersey

 1 than you have a chance to win the lottery. Okay.

 2   So just discouraging to buy the lottery tomorrow.

 3   But what most seriously, it is statistically

 4 significant and it means a lot. It means different

 5 prescribing behavior.

 6 Q.   So based on the strength of that test, you concluded that

 7 Janssen's speakers were more likely to prescribe Prezista and

 8 Intelence than non-speakers.

 9   Is that fair?

10 A.   Right.

11   For the purpose of communicating to the jury, I put in

12 the box at the bottom usually the conclusion from what the top

13 say. And here it say definitely the statistical result is so

14 strong so that, you know, prescribing behavior is definitely

15 different.

16 Q.   Now, let's take a look at -- did you do a different

17 analysis, sir, to look at the speakers' actual levels of

18 compensation, the amount that the speakers were paid and their

19 prescribing behavior?

20 A.   Yes.

21 Q.   Let's stop here for a moment, sir.

22   "Speakers who received" -- and this is in the box at

23 the top. "Speakers on the Promotional Speaker Bureau who

24 received more compensation prescribed more Prezista and

25 Intelence than speakers who received less compensation."

1   Do you see that?

2   A.   Yes.

3   Q.   Explain to the members of the jury, if you would, sir,

4   what you did initially to compare the amount of money that

5   speakers on the speaker bureau got versus the amount of

6   Prezista and Intelence that they prescribed.

7   A.   Yeah, one -- one way to analyze data is to try to

8   tabulate it. Tabulation really helps. If you look at 300

9   numbers, how much money they got, how much prescribed, you

10 really don't know what to do.

11   One way to do it is very simple. I -- this page -- and

12 you will see the next in a minute -- I decided to -- sorry --

13 separate the -- or not separate, divide the speakers to three

14 groups. Those who got less than 50,000, that's -- those who

15 got between 50 and 100 and those who got more than 100,000.

16   And then I did take a look at -- at prescribing. How

17 many of them are -- prescribe P and I. You can see that the

18 group of less than 50,000 prescribe only $1,200. And by the

19 way, one important thing here, this is an annual average

20 prescription. Why did they use annual? Because if one person

21 has a practice of -- for seven years and the other one is only

22 two years, there is a size bias and time bias. So the best

23 thing to do is per year.

24   So I did take the prescription per year opposed to

25 tabulate the compensation. And it turn out that the one with

United States District Court
District of New Jersey

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 1   less than 50 prescribe $1,200 per year.  The one with the more

 2   than 100 prescribe 183.

 3        Now, no doubt that this is one of the most telling

 4   pages, in my opinion.  I mean, not the -- really very excited

 5   or unexcited.  But when I look at it, I say, you have

 6   compensation at the bottom, you have prescription going up in

 7   the bar charts, and clearly, the one with the less than 50,

 8   there is no reason to believe that ones -- once somebody got

 9   less than 50,000 is prescribing very only 102.

10        So the same thing it's showing on the right-hand side

11   is the average.

12   Q.   Okay.

13        So on the left, again, we have the median.

14   A.   Right.

15   Q.   And on the right, we have the average.

16        And sorry to ask an obvious point, Professor.  What is

17   happening as the more doctors are getting paid?  What is

18   happening with their prescriptions?

19   A.   Going up.  That's -- you don't need Ph.D. in math or

20   statistics.  Somebody who's less than 50, prescribe 102.  One

21   is more than 100, prescribe 183.  Might be many reason.  But

22   it's definitely relationship between compensation and

23   prescription.

24   Q.   Let's take a look at speakers who received more

25   compensation prescribing more Prezista and Intelence than
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 1 speakers who received less compensation.

 2   All right, sir?

 3   Did you also take a look at what we just took a look at

 4 and categorized the compensation in three separate buckets?

 5 A.   Right.

 6   Instead of my judgment of less than 50 or 50 to 100, I

 7 said, forget it. I am going just to rank all the 300 of them,

 8 take the top compensation, one set of compensation, the middle

 9 doctors that got medium compensation, medium, and the one who

10 got the least. I just divided to three groups after ranking

11 them.

12   And you can see on the left-hand side, the green one

13 says "the bottom third." The bottom third prescribe 95,000

14 per year. This is the annual. Annual is per year.

15   On the right-hand side, we have basically almost

16 identical -- not identical, almost twice, perfectly twice as

17 much.

18   The one who got the top third prescribe 183,000.

19   So you talk about 90,000 for the bottom one and about

20 183 for the top one, no doubt this one is something that you

21 wouldn't expect to see a priori.

22 Q.   A priori?

23 A.   A priori means in advance.

24 Q.   Okay. Thank you, sir.

25 A.   Sorry.

1   Q.   That's a $10 word.

2   A.   Yeah. That's even more than the words that the lawyers

3   use.

4   Q.   Thank you, Professor.

5   "Higher speaker compensation linked to more Prezista

6   and Intelence prescriptions."

7   Do you see that?

8   A.   Yes.

9   Q.   Okay.

10   Did you now perform another statistical test to

11   eliminate chance?

12   A.   I wanted to -- correct, yes.

13   Q.   And what is a rank order correlation test?

14   Before you explain it to us, were you able to rank the

15   speakers in terms of their compensation from top to bottom?

16   A.   Yes. Sure.

17   Q.   Okay.

18   And then did you perform a statistical test to see if

19   there was a relationship between that ranking of compensation

20   and how much they prescribed?

21   A.   That's correct.

22   Q.   And explain how you did that, sir.

23   A.   The footnotes that most of us cannot see from far away

24   say it's called Spearman's Correlation. But I wanted to spare

25   this, you know, the word "Spearman." Sounds like a very

1   German test.

2   The idea is here very simple. And I tell you when

3   people are classically use this kind of test.

4   If you have 300 students and you rank them by the

5   number of hours that they prepared for a test --

6   Q.   That they studied?

7   A.   Studied for the test.

8   Q.   Okay.

9   A.   -- and you rank them also on the side with the grades

10   that they got. The number of hours that students, 300 student

11   invested preparing, and here are the grades.

12   Now, obviously, it's not a perfect correlation. Why?

13   Because some geniuses, they can have zero preparation and

14   always get the very good grade and the opposite. But the

15   majority of the people are spending some reasonable time, and

16   we can find the relationship.

17   If we want to know whether there is a relationship

18   between number of hours preparing for a test and the grade in

19   the test, this is the test. It's called rank order

20   correlation.

21   You rank the doctors based on their compensation, and

22   next to each of them, you write also how much they prescribed.

23   And you want to see whether the right-hand side is correlated

24   with the left-hand side. It's a very, very intuitive test, in

25   my opinion. I mean, I love this test because educators are

1   using it everywhere we can use it.

2   Now, in this case, I did it to the doctors,

3   compensation, and next to each doctor compensation, I wrote

4   the prescription, and I wanted to see whether the two are

5   actually correlated.

6   Q.   And what were the results of that test, sir, that we're

7   looking at on this slide 33?

8   A.   Yeah. Instead of the -- for this kind of thing that you

9   rank, instead of Zs that we talked earlier on, now we have a

10   T, but you should really worry what is the difference between

11   Z and T.

12   The T is almost identical in importance to the Z. If

13   the T is greater than 1.65, the test means there is a

14   significant -- statistically significant correlation between

15   compensation and prescription.

16   Q.   Okay.

17   So is it -- if the results are over 1.65, that means

18   something in statistics.

19   Is that right?

20   A.   It means more than something. It means that it's

21   statistically significant.

22   Q.   And what -- what was the result of this test that you

23   performed?

24   A.   This test indicate clearly that it's not a chance

25   correlation. The correlation between compensation and

```
 1  prescription is not a chance event.  It's -- there is

 2  something more than just by luck.  This one is correlated to

 3  that one.

 4       By the way, the correlation, if it's negative, it means

 5  they're inversely related.  If it's positive, obviously it's

 6  positively related.

 7  Q.  All right, sir.

 8       And let's change your attention now or shift your

 9  attention to the off-label.  That had to do with speaker

10  compensation for the anti-kickback claim.

11       Let's look at off-label analysis of prescribing

12  behavior of physicians.

13       Okay, sir?

14  A.  Yes.  Sure.

15  Q.  Now, sir, for this analysis, you set it up, and you look

16  at the top, and you say comparison groups.

17       Group one has a list of thousands of HIV patients

18  getting Prezista and Intelence during the same time period,

19  also government reimbursements and thousands of non-influenced

20  physicians, doctors who did not have contact with Janssen.

21       Is that right?

22  A.  That's a non-influenced, correct.

23  Q.  Okay.

24       And then on the right-hand side, you've got a group

25  with thousands of HIV patients getting Prezista and Intelence
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United States District Court
District of New Jersey

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 1  during the same time period with government reimbursement for

 2  the prescriptions and thousands of influenced physicians,

 3  doctors who went to speaking events, spoke on the speaker

 4  bureau, or received messages from Janssen's sales force.

 5        Is that right?

 6  A.    That's correct.

 7  Q.    Now, what is the primary difference between those two

 8  groups?

 9  A.    The primary difference given that it's a large number on

10  the left and the right -- the primary difference, that one

11  group had contact with Janssen, and the other one didn't have

12  contact with Janssen.

13  Q.    So what does comparing these two groups allow you to

14  isolate for?

15  A.    It's a -- one can find all kind of reason why a doctor

16  prescribed.  You can spend either the rest of your life just

17  talking about the factors and, you know, every person is

18  different.  I agree.  There is no reason about it not to

19  believe.  Every patient is special case.

20        But on the left-hand side, on the non-influence, we

21  have 38,000 people as we've seen in a minute.  On the

22  right-hand side, we have about 75,000 patients.  So 38,000 and

23  75,000 cannot be very different or unique.

24        The only thing -- the difference between these two

25  boxes is that one is influenced, and the other one is ran by
```

1   non-influenced, or actually the doctors are influenced versus

2   non-influenced. It's the same drug. It's the same time

3   period, thousands of people, government reimbursement.

4   And I can be, you know, cross-examined the rest of my

5   life on factors. Factors are important, but when you have

6   75,000, you don't tell me the people -- the 75,000 are very

7   different from the 38- just because one is influenced or

8   non-influenced.

9   It can be very -- Janssen factor really is the only

10   difference between the two.

11   Q.   Given the size of the number of patients involved -- in

12   each of the two groups and the number of doctors in each of

13   the two groups and otherwise similar factors, were you able to

14   isolate to compare the effect of Janssen's marketing?

15   A.   Absolutely.

16   Q.   We mentioned this briefly with Ian Dew when he was

17   describing the large volume of datasets, sir. Were you here

18   for that testimony of Ian Dew?

19   A.   Yes.

20   Q.   And I asked him about this, but now I'd like to ask you

21   about it as a professor of statistics.

22   Explain to us what the law of large numbers is and what

23   it means in your field.

24   A.   In plain English, the law of large numbers sounds very

25   scary to me, if I'm a lay person.

1   In plain English, it's very simple. It means if you

2   have 38,000 and 75,000, you cannot go to unique cases because

3   very few people can move average median of 75,000 or 38,000.

4   I mean, that's a lot of large number.

5   If you have a large number of observations -- we call

6   it in statistics -- in this case patients, the probability

7   that there are some very unique, you know, one eats lettuce,

8   the other one doesn't eat lettuce. Come on, give me a break.

9   It's not the case.

10   So that's what in plain English is the law of large

11   numbers. If there is -- if there is a difference between the

12   two, it's not because of unique few patients on. There is a

13   real difference between the two if you find.

14   Q.   Thank you, sir.

15   And now, again, just as a reminder, influenced

16   physicians were those that spoke at a Janssen speaking event

17   or attended one or received Janssen's marketing from the sales

18   force.

19   Correct?

20   A.   That's correct.

21   Q.   All right.

22   Now, let's take a look at this analysis of the

23   difference in the behavior between doctors who received

24   Janssen's marketing and their prescribing patterns.

25   All right?

1   A.   Yes.

2   Q.   Were you able to analyze, Professor, using statistics,

3   that the influenced physicians were more likely to prescribe

4   Prezista and Intelence off label than non-influenced

5   physicians?

6   A.   Yes.

7   Q.   Can you explain to the members of the jury what the

8   median ratio of off-label Prezista and Intelence tells us?

9   What does this tell us is the difference between the

10 prescribing patterns of doctors who have received Janssen's

11 marketing versus those who have not?

12 A.   Just to explain because after some time, I'm sure that

13 all these look all the same, the same bars, the same colors.

14 It's not the same.

15   Before I took how many were prescribed out of total

16 number of ARV, which means the -- sorry -- the HIV drug. Now,

17 we are in the off-label world.

18   What I did, I look at the ratio of off-label Prezista

19 and Intelence and divide it by all the Prezista and Intelence

20 Rx, what proportion of your Prezista and Intelence, leaving

21 out all of the other drugs, you are doing off-label. You mean

22 influenced versus non-influenced.

23   Now, you can see on the left-hand side the median for

24 the influenced is zero. It means that the typical person out

25 of the influenced physician, which is about 20,000 of them,

1 still doesn't do any off-label. None.

2   On the right-hand side, the influenced have already

3 13.2. Now, that's a big difference. I mean, median zero

4 means that at least 10,000 don't do any off-label. I don't

5 know the number until I look at the data.

6   But the median means rank them. The guy in the middle,

7 who is about 10,000, doesn't do any off-label. On the

8 right-hand side, we have the influenced, and they give one out

9 of a few -- 30 percent of the prescriptions off label.

10 Q.   So just to summarize, sir, the typical doctor who has not

11 had any contact with Janssen's marketing, prescribes zero

12 Prezista and Intelence off label.

13 A.   I am glad that you asked something to -- working with me.

14 I thought the word "typical," this gentleman. The median is

15 the word typical. We want to know the typical guy, and the

16 typical is a median, like we say about Michael Jordan and the

17 other guys.

18   The same thing is here. You are right. The typical

19 non-influenced does not do any off-label. They're in the

20 middle. There are some people, you know, that are high; maybe

21 they are doing a lot maybe, but very few. Majority of them

22 don't do.

23 Q.   And how about the typical influenced physician who's had

24 Janssen contact? They're prescribing one out of six or so,

25 one out of seven of every one of the off-label prescriptions

1   for Intelence?

2   A.   That's correct.   That's -- between one and six and one

3   and seven.

4   Q.   Professor, looking at this analysis, were you able to

5   determine a relationship between Janssen's marketing to

6   physicians and their behavior in prescribing Prezista and

7   Intelence off label?

8   A.   Yes.

9   Q.   And what was that relationship that you observed?

10 A.   The relationship-- in my opinion, the data indicates

11 nothing to do with me.   This is only data that I, you know,

12 summarized and ran -- ran some statistical test.   Definitely

13 indicates that there is a clear relationship.

14   I don't say any word -- other relationship is very

15 clear, that non-influenced have much less tendency, if not at

16 all, not to do off-label.

17   In contrast, the people that in the -- in the contact

18 with Janssen are doing much more off-label.

19 Q.   And did you apply -- without going back into the level of

20 detail, did you apply that same Z-Score test -- statistical

21 test to that relationship, the relationship between those

22 influenced doctors who prescribed off label and those who are

23 not influenced?

24   Did you apply the same statistical Z-Score test to that

25 relationship to determine if that was the result of luck or

United States District Court
District of New Jersey

1   chance?

2   A.   Yes.

3   Q.   And what was the outcome of that test?

4   A.   The outcome of this test -- to remind you, the test is

5   not on the median. It's on the averages. It's called test of

6   averages.

7   So I test whether it's 11.2 -- 11.2 percent for

8   non-influenced is statistically different than the 22.3.

9   Somebody might say, Oh, big deal, 11.22. No, it is a big deal

10   because thousands of people or patients are behind it.

11   And the test indicates it's strongly different. It

12   means there is a strong statistical significance to the

13   statement that these two are not the same. They're different.

14   Z of 26, it's -- I wouldn't say rare, but it's very unusual to

15   see it on this kind of data.

16   Q.   And, professor, it states here that the probability that

17   the difference between the averages happened by chance is less

18   than one in ten billion.

19   A.   You are better off betting on that one than buying the

20   lottery, right? Or buying the lottery is better than that

21   one. Sorry, folks.

22   Q.   Thank you.

23   A.   I was wrong.

24   Q.   Now, did you determine a relationship or did you analyze

25   behavior to determine whether speakers were more likely to

1 prescribe Prezista and Intelence off label than non-speakers?

2 A.   Yeah. Last one was influenced, I believe, right?

3 Q.   Yes, sir.

4 A.   Now we are at the speakers. I do the same -- perform the

5 same analysis, exactly the same, and can take a look here.

6 It's a ratio. You take for every doctor how many prescribed

7 off label, dividing by how many prescribed -- he or she

8 prescribed total.

9   That's what is tested here, and the idea is off-label

10 divided by total, the typical doctor, which is a

11 non-influenced -- the typical non-influenced doctor doesn't do

12 any off label. The median is zero. They do, but in the

13 middle -- the guy in the middle doesn't do any.

14 Q.   All right.

15   So the typical nonspeaker doesn't prescribe Prezista

16 and Intelence off-label at all during this time period.

17 A.   The typical. Now, some, they do, but you can see that

18 half of them -- at least half of them don't do at all.

19 That's -- the word "median" means half.

20 Q.   Okay.

21   And then when you're talking about speakers, let's look

22 at their prescribing behavior. The median speaker, what do

23 the typical speaker -- what percentage of off-label

24 prescriptions for Prezista and Intelence do they write?

25 A.   This is almost one-third. This is 30.2 percent of the

     1 speakers are doing off-label. That's the median, so if you

     2 take 300 speakers, 304, you say -- you arrange them.

     3   The percent in the middle, almost one out of three of

     4 his or her prescription are off-label. All right. If you do

     5 the same thing for the thousands of non-speakers, vast

     6 majority, at least half don't do it. It's more than half. I

     7 know. I look at the data.

     8 Q.   And so were you able to apply the Z-Score test to that

     9 relationship as well?

    10 A.   Yes. I did it, and it's the exactly the same. I went to

    11 10 billion because I wanted to save a few zeroes. The

    12 calculator even could not take this number. The 17 and 24 Z

    13 is a very, very low probability. It's even less than what

    14 they wrote here.

    15 Q.   So you eliminated the possibility that this was by

    16 chance?

    17 A.   And very unlikely to be by chance.

    18 Q.   Attendees, let's take a look at the attendees, the

    19 doctors, prescribers who attended these dinners or speaking

    20 events versus the speakers themselves.

    21   How about the attendees' tendency and their tendency to

    22 prescribe Prezista and Intelence off label?

    23 A.   I promise the jury I'm not going to put them to sleep, so

    24 I apologize. This is a third analysis, but I just divided it

    25 to influence speakers and up to this. This one here is the

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 1   same as before.  I'm not saving all of -- this is the same

 2   thing, but just for attendees.

 3         And the difference, the median non-attendee --

 4   non-attendee does not do any off-label.  The typical attendee

 5   is 18.1.  Almost one out of five prescription are off-label

 6   versus zero for non-attendee.

 7   Q.   Thank you, Professor.

 8         Did you do a Z-Score test to determine whether that

 9   relationship of non-attendees versus attendees was by chance?

10   A.   Same result.  The difference is -- between the two groups

11   or averages of two groups -- sorry -- is statistically

12   significant by far.

13   Q.   Thank you, Professor.

14         And as I understand it, the probability that that

15   relationship was the product of chance was also less than one

16   in ten billion.

17         Is that true?

18   A.   That's correct.

19   Q.   All right.

20         Now, let's take a look at the relationship between

21   marketing contacts, okay, the actual sales calls and visits

22   from Janssen's marketing -- excuse me -- Janssen's sales force

23   and those doctors' tendencies to write Prezista and Intelence

24   off label.

25         Okay?
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United States District Court
District of New Jersey

1 A.   Okay.

2 Q.   Did you analyze, Professor -- now we're not talking about

3 compensation. We're talking about the number of times that a

4 doctor was called upon by a Janssen sales representative.

5   Correct?

6 A.   That's right.

7 Q.   Let me just take a look at the top here. It says --

8 A.   Sorry for saying correct. The contact is more than just

9 the calls.

10 Q.   Thank you. Well done, sir.

11   Not just sales calls, but also speaking events and

12 attending?

13 A.   Speaking events, attending, calls. The biggest number is

14 obviously the number of calls. That's the reason I think that

15 the counsel say calls.

16 Q.   I'm sorry. Not phone calls. Visits to a doctor.

17 A.   Visit, right, right.

18 Q.   Okay.

19   And that was information that was obtained from

20 Janssen. That was the 620,000 sales calls that their sales

21 force made.

22   Right?

23 A.   Correct.

24 Q.   Physicians or doctors who received more Janssen marketing

25 contacts prescribed more off-label Prezista and Intelence.

United States District Court
District of New Jersey

1   Is that right?

2   A.   It's absolutely right. This -- this one -- you know,

3   sometimes in statistics, we plot some lines to see the

4   direction. You don't need to plot anything here because on

5   the left side you have zero. On the right-hand side of the

6   median, you have 32.2.

7   And what I did in this page, I tabulated them to 1, 2,

8   3, 4, 5 -- five groups. Number of contacts greater than 400,

9   it's not a typo. This is a correct number.

10   When I saw it the first time, called Ian and I said,

11   You must be kidding, something is wrong. Why? Well, what do

12   you mean by more then 400 contacts? He say -- he said,

13   Israel, you are naive. There are many more than 400, so...

14   Q.   Well, let me -- let me stop you there for a second, sir,

15   and let's just -- let's just get a frame of reference here.

16   There are -- there are doctors out of -- there are

17   doctors that Janssen's sales force called upon more than a

18   thousand times during this time period.

19   Correct?

20   A.   Champion is 1,620.

21   Q.   One doctor was visited by Janssen more than 1,600 times

22   during this time period?

23   A.   That's correct.

24   Q.   And other doctors over a thousand times?

25   A.   Very few of them were contacted only once, very small

United States District Court
District of New Jersey

1   percentage. The vast majority is more than two contacts. At

2   least 85, 87 percent have more than five contacts. You will

3   see it later on.

4   But no doubt that number of contacts make a difference

5   for prescribing. Somebody who gets more than 400, typical one

6   right here, the median is one out of three is off-label. You

7   have to remember what we're talking about, off-label.

8   On the left side, if you've got less than 50, you don't

9   do off-label at all. I mean, they didn't convince you yet.

10   I am sure that some people are doing it because you can

11   see on the right-hand side -- sorry -- there is 14.6, the

12   average. So some people are doing it, but the vast majority

13   of the -- of the speakers who get fewer contacts are

14   prescribing less.

15   The more contacts, the more promotions they have, the

16   more prescription -- they, I mean Janssen -- the more

17   prescriptions the doctors are writing.

18   Q.   Professor, what did the statistics from this body of data

19   show us with respect to the number of times that Janssen made

20   contact with a doctor and their likelihood of prescribing

21   Prezista and Intelence off label?

22   A.   I think that it's straightforward. The more contacts you

23   have, you as Janssen approaching a doctor, the more

24   prescribing the doctor does.

25   Q.   Prescribing off label?

United States District Court
District of New Jersey

1   A.   Off label, correct. Sorry.

2   Q.   Thank you.

3   Now, physicians who received more Janssen marketing

4   contacts prescribe more off-label Prezista and Intelence. Did

5   you just do the same analysis, but divide them into quartiles?

6   A.   That's correct. I like always -- this is my judgment,

7   most before, like less than 50 and so on, but somebody can

8   say, Why -- why 50? So I like to have quartiles.

9   It just takes them, takes the top quarter, the middle,

10   the second quartile, the third quarter -- quartile and the

11   bottom quartile.

12   Q.   All right, sir.

13   And when you divided them by quartile, did the same

14   trend hold, that the more contacts Janssen had with a doctor,

15   the more likely he or she was to prescribe Prezista and

16   Intelence off label?

17   A.   Right. I did take all the speakers. In this case, you

18   know, we talk about the median number of influence, and I rank

19   them, and I -- by quartile, and I rank them by number of

20   contacts.

21   And the ones that got the most contacts are the fourth

22   quartile. 28.2 percent is a median number of off-label

23   prescription that a physician does in this fourth quartile.

24   The one on the left, the median one is zero, not that he

25   doesn't do it at all, but it's zero.

United States District Court
District of New Jersey

1 Q.   And did you then perform the same rank order -- you

2 called it a Spearman correlation test -- the rank order

3 correlation test.

4   Did you perform that statistical test to determine

5 whether or not there was a relationship between marketing

6 contacts and off-label prescribing behavior?

7 A.   Yeah, I ran the same test that I told you about, about

8 the grades and the hours spent by students. What I did here,

9 I ranked them by contacts, and next to each contact the -- I

10 wrote the prescription, how much off-label prescription the

11 doctor did.

12   And the correlation is amazingly strong. It's like

13 31.9 is what we -- they call a T-value. You need 1.65 to give

14 you a feel to be significant. So 31 means it was all

15 likelihood. It's virtually certain.

16   Nothing is certain in life. I cannot promise you any

17 certainty, but it's virtually certain, a reasonable degree of

18 certainty that this is not a chance relationship. The more

19 contacts you have, the more off-label prescription you do.

20 Q.   Thank you, Professor.

21   Now, let's take a look specifically at the speakers'

22 off-label prescribing habits.

23   All right, sir?

24   It says at the top here of Slide 50, "Speakers wrote

25 over 20 percent." Just let me stop for a second.

United States District Court
District of New Jersey

1   There were approximately 300-plus speakers on these

2   speaking events -- Promotional Speaker Bureau during the time

3   period from 2006 to 2014.

4   Correct?

5   A.   That's correct.

6   Q.   And that's out of all physicians of -- 25,136 physicians

7   who prescribed antiretroviral drugs.

8   Correct?

9   A.   No. That's 25,000 that did at least one POI, Intelence

10   or Prezista.

11   Q.   Thank you. Not even --

12   A.   Not even ARV.

13   Q.   Not even antiretroviral, but specifically Prezista and --

14   A.   Right. I apologize for correcting you sometimes.

15   Q.   That's okay. Thank you, Professor.

16   So 304 speakers you looked at compared to 25,000 --

17   more than 25,000 who prescribed Prezista and Intelence.

18   Correct?

19   A.   That's correct.

20   Q.   And so that was only -- so the speakers comprised only

21   1.2 percent of all the doctors who were prescribing Prezista

22   and Intelence during this time period.

23   Is that right?

24   A.   That's right.

25   Q.   And what percentage of off-label prescriptions did the

United States District Court
District of New Jersey

1   speakers account for out of all the off-label prescriptions

2   that were reimbursed by the government?

3   A.   20 percent. So it means 1 out of 100 of the doctors

4   prescribe one out of five of the off-label.

5   Q.   So what does that tell you about the relationship between

6   an average speaker on the Promotional Speaker Bureau and the

7   number of times -- how much more likely they were to prescribe

8   Prezista and Intelence off-label than a nonspeaker?

9   A.   It's a very simple thing. You take the 20, divide by 1.

10   It's about 17. I wrote it at the bottom here. I divide by 2.

11   But I -- but I think the better -- in my opinion, if I want to

12   explain to somebody what's really relatively unique here, that

13   you have 1 over 100 of the doctors doing 1 out of 5 of the

14   off-label. That's -- that's very, very unusual.

15   Q.   Thank you, sir.

16   We can see that graphically displayed on Slide 51.

17   Speakers, as a percentage of all physicians, was 1.2 percent,

18   but they prescribed 1 out of 5 of every off-label Prezista and

19   Intelence prescription.

20   Is that right?

21   A.   That's correct.

22   Q.   Now, let's compare them, sir, to doctors who had

23   initiated what I was saying earlier, at least one

24   antiretroviral drug for a patient.

25   Okay?

United States District Court
District of New Jersey

1   A.   Okay.

2   Q.   It says at the top, "Influenced physicians initiated over

3   65 percent of patients on Prezista."

4   Do you see that?

5   A.   Yes.

6   Q.   All right.

7   Tell us about what we're observing in this -- this

8   relationship, this comparison, and how it shows a relationship

9   for the doctors' prescribing habits.

10   A.   Yeah. On the left-hand side, you have the blue bar

11   chart. It's basically telling you that I took the influenced

12   physician and divided by all physician who did at least one

13   ARV. One ARV means any drug for HIV. That's ARV. So that's

14   about 11 percent.

15   However, the influenced physician also initiated 65.64

16   percent of the -- of the Prezista. This page is only for

17   Prezista. It's one of the first ones that I divided the

18   Prezista and Intelence in my analysis. So they do two-third,

19   initiate two-third of them, even though the 1 out of 10 of the

20   physicians do at least one ARV.

21   Q.   So one more time, sir.

22   The influenced physicians are 11 percent of all doctors

23   in the nation who prescribe antiretroviral drugs.

24   A.   Right.

25   Q.   But they account for 65 percent of the Prezista and

United States District Court
District of New Jersey

1   Intelence -- excuse me -- of the Prezista prescriptions.

2   Is that right?

3   A.   Right. I think that the margins are a little bit

4   difficult to read. I don't know from the jury side what they

5   see, but one of the footnote 2 say they basically initiated

6   55,879 out of 85,000. The 65 percent is 55,000 over 85. So

7   85 was the number that they initiated Prezista.

8   They -- they're responsible for 55,000 out of the

9   85,000, these influenced physician.

10 Q.   And let's take a look at the same for Intelence.

11   What was the relationship that you observed between

12 influenced physicians and their ratio of prescribing

13 Intelence?

14 A.   Yeah. Just to save time, it's basically the same. It's

15 11 percent of 69.

16   I did take a look at what percentage of the -- at least

17 one ARV of these doctors and then what percentage of Intelence

18 was initiated by them. That's almost 70 percent of all

19 initiation was by these doctors.

20 Q.   All right.

21   Now, Professor, there is a -- an expert witness who the

22 members of the jury may hear from in this case who Janssen has

23 hired in part to critique your analysis. That's Dr. Jena.

24 A.   Yes.

25 Q.   Do you understand that?

United States District Court
District of New Jersey

1 A.   Oh, yeah.

2 Q.   All right, sir.

3   And so you've had the ability to provide your opinions

4 and see Dr. Jena's response to some of your opinions that the

5 jurors may hear from.

6   Fair?

7 A.   Correct. Not all of them, but at least some response.

8 Q.   At least some of them.

9   And let's take a look at what you term Janssen's

10 incorrect statements about the impact of its own marketing.

11   Okay, sir?

12 A.   Okay.

13   THE COURT: Mr. Marketos, before we get into this

14 topic, is now a good point to take a short break?

15   MR. MARKETOS: Absolutely, Your Honor.

16   THE COURT: All right. Let's do this, folks: We're

17 going to take a ten-minute recess. Everybody go stretch and

18 then we'll reconvene.

19   (Jury exits the courtroom.)

20   (A short recess occurred.)

21   THE COURT: Remain seated.

22   We ready, Mr. Marketos?

23   MR. MARKETOS: Yes, Your Honor.

24   THE COURT: All right, Kim. Let's get the jurors

25 back.

United States District Court
District of New Jersey

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 1              THE DEPUTY COURT CLERK:  All rise.

 2          (Jury enters the courtroom.)

 3              THE COURT:  Everybody be seated.

 4          And, Mr. Marketos, whenever you're ready to proceed,

 5   you may.

 6          And Professor, Shaked, just as a reminder, you're still

 7   under oath from earlier in the break.  Okay?

 8              THE WITNESS:  Sure.

 9              THE COURT:  All right.

10              MR. MARKETOS:  Thank you, Your Honor.

11   BY MR. MARKETOS:

12   Q.   Professor Shaked, before the break, we were discussing

13   some of Janssen's expert's contentions.  Dr. Jena's --

14   essentially his rebuttal to your opinions that you're offering

15   in this case.

16          Do you recall that?

17   A.   Yes.

18   Q.   And as I understand it, sir, and Dr. Jena will say,

19   perhaps, that Janssen's marketing maybe doesn't affect

20   physicians' prescribing behavior.

21          Is that generally your understanding of his position as

22   well?

23   A.   I think that -- that -- that type of analyze as presented

24   corroborate many of the testimonies that I read before.  I am

25   not relying on any testimony, but just to tell you that it's
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United States District Court
District of New Jersey

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 1  definitely wrong.

 2        There is a relationship between Janssen promotion and

 3  the prescription of off-label by speakers and non-speakers.

 4  Q.   Yes, sir.

 5        You're referring to testimony from this trial that you

 6  believe corroborates the statistical analysis that you've

 7  performed.

 8        Is that correct?

 9  A.   That's correct.  I also read about seven or eight

10  deposition.

11  Q.   Deposition testimony.

12  A.   Right.

13  Q.   But is it your understanding, Professor, that Dr. Jena,

14  Janssen's expert witness in this case, contends that Janssen's

15  marketing maybe doesn't impact physicians' prescribing

16  behavior?

17        Is that your understanding of his contention?

18  A.   Yes.

19  Q.   If we take a look at this slide, we've got a response

20  here, your response, and you've broken out for us the number

21  of marketing contacts that Janssen had with a specific

22  influenced physician on the left and then the number of

23  contacts or the percent of influenced physicians on the

24  right-hand side.

25        Do you see that, sir?
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United States District Court
District of New Jersey

1 A.   Yes.

2 Q.   And the reason I ask is, if, for instance, someone were

3 to ask you, well, what about the doctors that were only

4 contacted one time by Janssen's marketing? All right. What

5 percentage of the influenced physicians were only contacted by

6 Janssen one time?

7 A.   6.3 percent.

8 Q.   All right.

9   And we can see that at the top here. Marketing

10 contacts, 6.3 percent. That is 328 doctors were contacted

11 only one time, according to Janssen's records.

12   Is that correct?

13 A.   Yes.

14 Q.   And that's 6.3 percent of the total because the total

15 number of influenced physicians is 5,177.

16 A.   That's correct.

17 Q.   Right?

18   Okay.

19   How about -- let's take a look at the distribution

20 here. What does the typical doctor, just based on Janssen's

21 own database of calls, speaking events and attendees at

22 speaking events, what does the typical doctor show for the

23 number of times he or she was contacted or influenced by

24 Janssen?

25 A.   Anywhere between 50 and 100 times.

1 Q.   So if we look at the median number of Janssen marketing

2 contacts, you see 85 down there at the bottom, sir?

3 A.   Right. And 85 is the median.

4 Q.   So 85 is the median.

5   Is that the typical doctor based on your statistical

6 analysis?

7 A.   Yeah. If we just rank all the doctors based on the

8 number of times that Janssen contacted them, the person in the

9 middle would be contacted 85 times.

10 Q.   And then, on average, the average doctor would have how

11 many contacts with a Janssen sales representative or the

12 speaker bureau?

13 A.   Yeah. 135. But that -- the 85, I think, is much more

14 telling.

15 Q.   Okay.

16 A.   That's enough. In terms of contacts, it's very large.

17 Q.   In terms of contacts, it's very large?

18 A.   I am not an expert in how many times you call a doctor,

19 but somebody who calls a doctor every day for eight years,

20 that's a lot.

21 Q.   If we -- and, again, you reminded us earlier that there

22 are some doctors, for instance, that were contacted or had

23 more than a thousand contacts.

24   Right? Do you recall that?

25 A.   Yeah. Yeah.

United States District Court
District of New Jersey

1   Q.   And then some doctors, of course, had fewer contacts.

2   Right, sir?

3   A.   Yeah. The doctor that was testifying last week, it was

4   1,014 times contacted.

5   Q.   Dr. Hsu, who Janssen called as a witness in case, we saw

6   him on television, you saw that he was contacted more than a

7   thousand times by -- by Janssen, either through the speaker

8   bureau or with a visit from a sales representative.

9   Is that right?

10   A.   Yeah. 1,014 times.

11   Q.   All right, sir.

12   Let's take a look, "Dividing influenced physicians to

13   four equal size groups based on the number of received Janssen

14   marketing contacts."

15   What is your response to -- and we've already seen this

16   slide. Let's be clear. This slide was something you

17   discussed to show the relationship between a number of

18   contacts a doctor had and their tendencies to prescribe

19   off-label.

20   What is your response to Dr. Jena when he says there's

21   probably no relationship or there may not be a relationship

22   between Janssen's marketing and a physician's prescribing

23   habits?

24   A.   I just -- all I have to do is to show this bar chart

25   presentation to somebody with a third-party objective and say,

1   what is here? Everybody can see that, the more contacts you

2   have, you have more off-label prescription. It's -- it goes

3   without saying.

4   Q.   And is that the similar response you would have if we

5   take a look at the typical physician -- or non-influenced

6   versus the typical influenced physician for Janssen?

7   A.   Yes. Correct.

8   Q.   But, sir, you're testifying here as an expert on

9   statistics and economics in a court in this case, and Dr. Jena

10 has also been hired by Janssen to do the same thing.

11   What about in real life back during 2006 to 2014? Did

12 Janssen itself hire its own experts to take a look at the

13 impact on prescribing behavior that its own efforts had in

14 real life?

15 A.   Absolutely.

16 Q.   What -- so there's a reference here, "PILM, return on

17 investment analysis of Janssen's marketing."

18   PILM, is that an acronym for a company called Partners

19 in Loyalty Marketing?

20 A.   That's correct.

21 Q.   And, Professor, is it your understanding that Janssen and

22 its marketing department paid this company to do a real-time

23 analysis of the effect of its marketing on its sales?

24 A.   Yeah. This is a real consulting company. They're not

25 charity. Obviously, they got paid.

1   Q.   And did you get access to these documents that are in

2   evidence in this case to determine whether or not it

3   corroborated your analysis of these relationships?

4   A.   Yes.

5   Q.   And if you take a look at -- again, you say "Partners in

6   Loyalty Marketing is a marketing consulting firm, and it

7   analyzes return on investment, ROI, for marketing programs and

8   various industries."

9   Correct, sir?

10 A.   Yes.

11 Q.   And Janssen hired this unrelated third party to conduct

12 an evaluation of the effectiveness of its marketing

13 initiatives.

14   Is that right?

15 A.   That's correct, including the speaker program.

16 Q.   Including the speaker program.

17   So let's take a look at this screenshot from one of

18 those reports. It says -- or PILM itself says, "PILM

19 evaluates the number of prescribing versus non-prescribing

20 physicians in pre- and post-program periods to help answer:

21 Do new physicians start to write post-program exposure? Are

22 current prescribers continuing to write or writing more

23 post-program exposure?"

24   Do you see that?

25 A.   Yeah. And that's -- I want to emphasize when I put this

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 1  slide together and I screenshot, this is out like -- sorry --

 2  straight out of the report.  They say that, you know, we

 3  basically want to know what is what they call "lift."  Lift

 4  mean increase the number of prescription as a result of the

 5  program.

 6  Q.   So this screenshot is coming from PILM's own report, and

 7  they want to see if there's lift, an impact in the speaker

 8  program itself and how physicians write prescriptions before

 9  and after the program.

10  A.   Absolutely.  That's what is written here.

11  Q.   All right.

12       And, again, sir, this was -- was this something that

13  was done for this litigation, or was this something that

14  Janssen actually performed an analysis in real life in real

15  time?

16  A.   Not only that they did it in real life, but every three

17  or four months, I found period of few years with lots of

18  reports, one after the other.  You know, November and then

19  March and then whatever, October, they wrote more than one

20  report.

21       So Janssen retained them to analyze the profitability

22  of the speaker program.  No doubt about that.  That's --

23  that's the purpose.

24  Q.   And if we take a look at this screenshot, according to

25  all -- this is, again, from a PILM report -- they looked at
```

1   incremental prescriptions and sales against their own costs to

2   calculate the true return on investment for Janssen.

3   Do you see that?

4   A.   Yes.

5   Q.   And it was, according to PILM, Partners in Loyalty

6   Marketing, a transparent model that has been approved by

7   Janssen's finance and marketing departments.

8   Do you see that?

9   A.   Yes.

10 Q.   Let's --

11 A.   Now, what I want to say, that's very unusual. When you

12 consult somebody, you working, you sit down as management,

13 learn the company and you get an approval for your models.

14 That's what this is. The models were approved by the

15 marketing and finance department of Janssen.

16 Q.   And that's not unusual.

17   Right?

18 A.   For consultant, no. That's what I do when I consult. I

19 first one to know management, that they will understand what

20 I'm going to do. And, you know, just the same opinion as me,

21 that's what's relevant to analyze.

22   So they actually consulted Janssen and got the approval

23 for their motives.

24 Q.   So they -- PILM sat down with Janssen and their financing

25 and marketing departments and got approval for the models that

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 1  we're looking at.

 2  A.   I was not there, but it's very likely to be the case that

 3  they sat together, honestly.

 4  Q.   Okay.

 5       Janssen's speaker program results are reflected just

 6  for a period of time, January to November of 2011, and it

 7  states that each dollar invested in the program returned

 8  $2.90.

 9       Do you see that, sir?

10  A.   Yeah.  They invested 2.6 million and they got 7.7 back.

11  Q.   All right.

12       So that's called a total net trade sales lift and a

13  total return on investment of $2.90 for every one invested.

14       Correct?

15  A.   Right.

16       And the lift in many places in the report also refer to

17  as "incremental."

18  Q.   All right, sir.

19       And you can also see that there's a prescription lift

20  per participant.  The number of additional prescriptions that

21  were written for these drugs associated with participants in

22  the speaker program.

23       Do you see that?

24  A.   That's correct.

25  Q.   All right.
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1   And that turns into dollars.

2   A.   That's dollars, because on the average, every

3   prescription of this company, is about Janssen --

4   approximately -- between 690 and $750 per prescription.

5   Q.   So each prescription is worth about 690 to $750. That's

6   just for a 90-day prescription.

7   A.   Correct.

8   Q.   And those are -- those are per participant the number of

9   prescriptions that they're writing additionally.

10   A.   Yeah. You have to multiply the 700 by 5. You talk about

11   3,500 to $4,000 per participant's return.

12   Q.   Thank you, Professor.

13   Janssen's speaker program results for January to

14   November of 2012, a different time period, PILM analyzed an

15   additional net trade sales lift of $4.3 million, and now it's

16   a return on investment of more than $3 for every dollar

17   invested.

18   Do you see that?

19   A.   Yes. It varies over time. Anywhere, 2, 9, 3, 5, all

20   kind of numbers, but that's the range, more or less.

21   Q.   And then for the Janssen's speaker program results for

22   the first quarter of 2013, you saw just for that first

23   quarter, return on investment of $2.84 for every dollar they

24   invested.

25   Right, sir?

United States District Court
District of New Jersey

1 A.   That's correct.

2 Q.   Now, let's take a look at what Partners in Loyalty

3 Marketing, after it performed these analyses, concluded about

4 Janssen's speaker programs themselves back during the time

5 period in question.

6   Okay, sir?

7   Did PILM conclude "Speaker programs are an effective

8 way to make a lasting impact on prescribing behavior"?

9 A.   Which totally -- totally negates what you mentioned about

10 Dr. Jena. Dr. Jena say it doesn't affect. Even third party,

11 unrelated, objective one, concluded that these programs do

12 affect the prescribing behavior. That's the best -- in my

13 opinion, it's just, you know, black and white. It's written

14 there.

15 Q.   So just to be clear, Janssen's consulting experts in real

16 time concluded that speaker programs are an effective way to

17 make a lasting impact on prescribing behavior.

18   Right?

19 A.   Yeah. That's what the report said.

20 Q.   But Janssen's testifying expert in this case disagrees

21 with Janssen's real-time experts on this conclusion?

22 A.   I think, in my opinion as an expert, conclusion that was

23 at real time at that time and now in 2024 say it's not, I

24 don't think it's very -- I'm not here to opine on Dr. Jena,

25 whether he is credible or not. But this statement that I saw

1 in all these reports clearly indicate the program aimed to

2 increase lift and works well.

3 Q.   So it aimed to increase return on investment,

4 prescription lift and it accomplished that task.

5 A.   That's correct.

6 Q.   All right, sir.

7   And it wasn't just for the speaker program. Partners

8 in Loyalty Marketing also analyzed the effectiveness of

9 Janssen's sales force and their visits to doctors.

10   Do you see that, sir?

11 A.   Yes.

12 Q.   So this is, again, another screenshot from the PILM

13 report, and it states "110 sales representatives called on

14 4,925 targets" -- that's doctors, prescribers.

15   Right, sir?

16 A.   Yes. Just to emphasize, the 4,925 is not number of

17 calls. It's the number of targets they call. They might have

18 10 or 15 calls per target.

19 Q.   Yes, sir.

20   So 110 sales representatives visited almost 5,000

21 doctors or prescribers in 2012, and they did so multiple

22 times.

23   Right?

24 A.   Most likely, yes.

25 Q.   And then each health care provider, each doctor,

1 generated 5.61 incremental, additional prescriptions, topping

2 all programs.

3   Do you see that?

4 A.   Yes.

5 Q.   And then Janssen's experts at the time stated that "This

6 is the strongest sales force lift that PILM has seen across

7 evaluated pharmaceutical brands."

8   Do you see that?

9 A.   Yeah. I -- I was very impressed. Doing well.

10 Q.   All right, sir.

11   Was there also another interesting conclusion that

12 Partners in Loyalty Marketing reached back in real time about

13 speakers from the Intelence program, or the attendees and

14 speakers at the Intelence speaker bureau, and how that would

15 actually impact the additional prescriptions that were written

16 for Prezista?

17 A.   Right. This is a screenshot. Just to emphasize, I know

18 that people know to read, but I tended to, when I seem to

19 forget, this is screenshot from the company.

20 Q.   A screenshot from PILM's own --

21 A.   From the consulting company.

22   Sorry, yeah.

23 Q.   All right, sir.

24   And it says, "Interestingly, Intelence speaker programs

25 also had impact on Prezista prescription lift, 13.72

United States District Court
District of New Jersey

1 prescriptions per health care provider."

2   Do you see that?

3 A.   Yes.

4 Q.   And does that say anything to you about prescribing

5 behavior associated with brand loyalty or familiarity with one

6 pharmaceutical company's drugs?

7 A.   They no doubt that the brand loyalty makes a difference.

8 I'm not expert in brands, but you can see that they say that

9 you can lecture about a product of the company, and it does,

10 what you call a Spearman effect, on the other product. It

11 means somebody's lecture on Prezista might move Intelence and

12 vice versa. And that's what they say the crossover or

13 Spear-over or from one brand to the other.

14   And remember also that Intelence was not there until

15 January 2008. So for the first one and a half year, it was

16 only Prezista. Only then it became the course.

17 Q.   Thank you, Professor.

18   I'd like to turn your attention now from the behavioral

19 analysis and the statistical analysis that you performed to

20 your calculation of damages to the government associated with

21 a payment of kickbacks and Janssen's off-label marketing

22 efforts for Prezista and Intelence.

23   Okay, sir?

24 A.   Sure.

25 Q.   Now, we saw this slide earlier. The kickbacks were

 1   associated with Janssen providing inducements or rewards for

 2   speakers on the speaker bureau, only focused on the speakers

 3   themselves.

 4   Is that right?

 5   A.   Yes.

 6   Q.   And then analyzing the effect; that is, the speakers

 7   prescriptions for Prezista and Intelence that were reimbursed

 8   by government payors.

 9   Right, sir?

10   A.   That's correct.

11   Q.   Okay.

12   And then on the off-label marketing side, we've got

13   Janssen marketing off-label to physicians and then the effect

14   those influenced physicians being the first writer initiating

15   an off-label prescription for Prezista and Intelence.

16   Right?

17   A.   That's correct.

18   Q.   So let's take a look at the kickback damages calculation.

19   Were you -- did you assume that once a speaker was paid

20   by Janssen to speak that all prescriptions for Prezista and

21   Intelence made by that speaker that were reimbursed by the

22   government are considered damages to the government?

23   A.   Yes. From the first time the person speak -- spoke or

24   give delivery -- delivered the speech forward.

25   Q.   And were you able to tabulate or tally from the data that

 1 was provided from Medicare, Medicaid, ADAP, the number of

 2 prescriptions that speakers on the speaker bureau wrote for

 3 Prezista and Intelence?

 4 A.   Yes.

 5 Q.   And, of course, during the time period in question, 2006

 6 to 2014.

 7   Is that right?

 8 A.   From January 2016 to December 2014.

 9 Q.   Sorry. January 2006?

10 A.   '6 to December 2014.

11 Q.   Okay. Thank you, sir.

12   And we've got kickback claims. Is that the number of

13 claims for reimbursement that were submitted to government

14 payors associated with the kickback allegations in this case?

15 A.   Yes.

16 Q.   And that number of claims that were submitted for

17 reimbursement for those prescriptions total 435,042.

18   Is that right?

19 A.   That's correct.

20 Q.   And then with respect to the money, the dollar amount of

21 the reimbursements paid by government payors, what was the

22 amount of kickback damages?

23 A.   Indicated $327.2 million.

24 Q.   Thank you, sir.

25   Now, let me turn your attention to the off-label

United States District Court
District of New Jersey

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 1  claims.  Of course there are four different claims for

 2  off-label that the members of the jury have heard during the

 3  course of this case with respect to Janssen's marketing

 4  efforts.

 5       That's the -- number one is the Prezista, the lipid

 6  issue associated with the allegations of minimizing or

 7  misrepresenting the side effects of that drug.

 8       Do you understand that?

 9  A.   Yes.

10  Q.   And then the second is Prezista's targeting of

11  treatment-naive patients before they have a label for

12  treatment-naive patients in 2008.

13       Right, sir?

14  A.   Yes.  That's correct.

15  Q.   And then third, Intelence treatment-naive, that is during

16  the entire time period that Intelence had its label, efforts

17  to market for treatment-naive patients.

18       Do you understand that?

19  A.   Yes.

20  Q.   Because Intelence never had a treatment-naive label?

21  A.   Never was approved.

22  Q.   And then finally, Intelence for once-daily dosing.

23       Your understanding is that those allegations are it was

24  never approved for once-daily dosing?

25       Is that right?
```

United States District Court
District of New Jersey

1 A.   That's correct. I mentioned it earlier. These two were

2 never approved.

3 Q.   And so, sir, on the -- when you're looking at Slide 72

4 here on the left-hand side, you've got off-label -- all

5 off-label -- I shouldn't say on the left-hand side -- excuse

6 me -- at the top in the circle at the top, all off-label

7 Prezista and Intelence prescriptions.

8   Do you see that?

9 A.   Yes.

10 Q.   Were those all identified off-label Prezista and

11 Intelence prescriptions from all government payors and the

12 databases?

13 A.   That's correct.

14 Q.   And then on the left, there is off-label Prezista and

15 Intelence prescriptions initiated by non-influenced

16 physicians.

17   Do you see that?

18 A.   Yes.

19 Q.   Were those considered damages that you're asking the

20 members of the jury to award back to the federal government?

21 A.   Absolutely not.

22 Q.   Okay.

23 A.   Only those that were initiated by influenced.

24 Q.   So on the right-hand side, off-label Prezista and

25 Intelence prescriptions initiated by influenced physicians,

 1 were those considered for off-label damages or damages to the

 2 government payors associated with off-label prescriptions from

 3 influenced physicians?

 4 A.   Correct.

 5 Q.   All right.

 6   So for our purposes, Professor, we're looking only at

 7 the arm of the analysis on the right.

 8 A.   Initiated -- just to modify -- initiated -- always

 9 initiated by influence, but even adopted by noninfluence, what

10 we call attributed, is also part of the damages.

11 Q.   And we'll get to that in a moment.

12 A.   Oh, okay. Sorry.

13 Q.   That's fine.

14   It's initiated prescriptions, and then those that

15 follow.

16   Is that fair?

17 A.   Right.

18 Q.   Okay.

19   So out of all government Prezista and Intelence -- all

20 government-reimbursed Prezista and Intelence prescriptions,

21 there were 2.95 billion, you've told us.

22   Is that correct, sir?

23 A.   That's correct.

24 Q.   All right.

25   And then out of all of the off-label Prezista and

```
 1  Intelence prescriptions, off-label is a subset of the

 2  government Prezista and Intelence prescriptions in total.

 3        Right, sir?

 4  A.   That's correct.

 5  Q.   And let me make sure I -- I frame this accurately.

 6        So in the yellow circle, we've got all government

 7  Prezista and Intelence prescriptions sales.  Whether it's on

 8  label or off label, that's the amount that the government

 9  payors reimbursed for Prezista and Intelence prescriptions

10  between 2006 and 2014.

11        Correct?

12  A.   That's correct.

13  Q.   All right.

14        That's $2.95 billion.

15        Correct?

16  A.   Yes.

17  Q.   All right.

18        And then off-label prescriptions within that -- within

19  that universe is a subset; is that fair?

20  A.   Right.  The blue one you're talking about?  Yeah.

21  Q.   Yes, sir.  The blue one.

22  A.   Right.

23  Q.   And then within the blue circle, you've got off-label

24  prescriptions initiated by influenced physicians.

25        Do you see that?
```

1   A.   Yes.

2   Q.   And that totals what amount, sir?

3   A. $446.7 million.

4   Q.   That's the amount that's reimbursed by government payors,

5   Medicare, Medicaid and ADAP, for off-label prescriptions of

6   Prezista and Intelence written or initiated?

7   A.   Initiated.

8   Q.   Thank you.

9   Initiated by influenced physicians.

10   Correct?

11   A.   Correct.

12   Q.   And what is the number of off-label claims associated

13   with the off-label damages?

14   A.   This 446.7 million representing almost 600,000 claims.

15   In this case 593,996 off-label claims.

16   Q.   So the number of off-label claims submitted to government

17   payors that turned into dollars, the number of off-label

18   claims was 593,996 initiated by an influenced physician.

19   Right, sir?

20   A.   Yes.

21   Q.   And or attributed to an initiated physician.

22   Right?

23   A.   Correct. In both cases it's initiated by the influenced.

24   Q.   Thank you, sir.

25   A.   I'll say -- I'll say if adopted by somebody this was

United States District Court
District of New Jersey

1   initiated by.

2   Q.   Thank you, sir.

3   So we've got reimbursed by government payors for

4   Medicare, Medicaid, and ADAP, and we've got Prezista lipid

5   claims and Prezista treatment-naive claims, and that totals

6   Prezista off-label damages, and then you've got the same below

7   for Intelence.

8   Do you see that?

9   A.   That's correct.

10 Q.   And now let me ask you this, sir: For the Prezista

11 treatment-naive claims, you've said that there were --

12 conservatively excluded certain off-label damages.

13   Right, sir?

14 A.   Yes.

15 Q.   All right.

16   So, for instance, you understand that Prezista was

17 prescribed for a very narrow segment of the patient

18 population.

19   Is that right?

20 A.   For treatment-naive, correct.

21 Q.   But did you only calculate those damages associated with

22 Prezista being prescribed for treatment-naive patients as

23 opposed to treatment-experienced patients that did not meet

24 the criteria for Prezista?

25 A.   I didn't understand the question.

United States District Court
District of New Jersey

1 Q. I didn't understand it either. I'm going to try it

2 again. Let's try it this way.

3   Were there patients that were treatment-experienced

4 patients but did not have two or more antiretroviral failures

5 such that they met the criteria for Prezista prescription?

6 A. Yes.

7 Q. All right.

8   So the E through the G segment in what we've been

9 looking at throughout this trial.

10   Right?

11 A. Yes.

12 Q. Did you -- were those included in your analysis or

13 excluded?

14 A. No, I didn't use two or more. It's not -- I

15 conservatively decided not to go with the two or more and say

16 one more.

17 Q. Okay, sir.

18   So ultimately there's a Prezista treatment-naive claim,

19 and a Prezista lipid claim, and you've totaled those on the

20 right for off-label damages of $414.3 million?

21   Is that right?

22 A. I assumed that you know what you say. I just want to say

23 in my words to make sure that it's correct.

24   There is 414.3 million say Prezista lipids. There is

25 1.9 Prezista naive, and I said, Okay, forget 1.9. Kind of

United States District Court
District of New Jersey

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 1   conservatively I assumed that -- I'm not sure how many

 2   overlap; might be somebody there.  I didn't feel -- I said,

 3   Okay, let's do 414.3, not that the 1.9 is wrong.

 4        But I decided not to add this too, but just to add the

 5   414.3.

 6   Q.   Thank you, sir.  You said it better than I could.

 7        So it's possible that somebody was prescribed Prezista

 8   for -- who had a lipid issue who should not have been but that

 9   that person also was a treatment-naive patient?

10   A.   That's exactly it.

11   Q.   So those claims might overlap.  So what did you do with

12   the $1.9 million?

13   A.   Took it out.

14   Q.   You just took it out of your analysis.

15        Is that fair?

16   A.   That's correct.  Not that I say -- I don't talk about the

17   legal and all this allegation, but I say numerically, I

18   decided not to account for it.  I don't say it's not important

19   or anything like that.

20   Q.   I understand, Professor.

21        So as far as your analysis for the members of the jury,

22   mathematically you removed that number from your calculation.

23        Is that fair?

24   A.   That's correct.

25   Q.   And with respect to Intelence once-daily dosing and
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1   Intelence treatment-naive, did you do the same conservative

2   estimate and decide to eliminate from your calculation the

3   16.4 million?

4   A.   I didn't count it as part of my damages.

5   Q.   Is that because of the potential for overlap and your

6   efforts to be conservative?

7   A.   It was potential. We checked it. I am pretty sure that

8   that is clean, but elected not to include the 16.4 anyway.

9   Q.   All right.

10   So the total for Intelence off-label damages is

11   32.4 million.

12   Do you see that, sir?

13   A.   That's correct.

14   Q.   All right, sir.

15   Now, there was a reference -- at one point hypoglycemic

16   was run in the medical diagnostic codes, and it was pointed

17   out that hypoglycemia might not perfectly correlate with the

18   lipid issue.

19   Do you recall that?

20   A.   Sure.

21   Q.   Okay.

22   Did you correct for that? Did you remove any analyses

23   associated with hypoglycemia from your calculations?

24   A.   Yeah, I did it a few years ago, sent to the other side

25   some correction. Obviously it's -- none of that is here.

1 This is already past history.

2 Q. Okay, sir.

3   And so the $414.3 million excludes any reference to the

4 hypoglycemia?

5 A. Absolutely. Nothing to do with it.

6 Q. All right.

7   Now, once you have calculated the kickback damages of

8 the $327.2 million and the off-label damages of 446.7 million,

9 was there a potential overlap?

10   And what I mean by that is, sir, is it possible that

11 one of the speakers on the speaker bureau wrote an off-label

12 prescription associated with a Prezista lipid issue or an

13 Intelence once-daily dosing issue?

14 A. Yeah, that's definitely a possibility. In order to avoid

15 double counting, what it's called, to count twice the same

16 amount, I did what I -- it's a scary word, de-duplication.

17 De-duplication means you avoid double counting.

18   So you take out the 84 -- 84.8 million that were both

19 in the kickbacks and the off-label, not to account twice for

20 them.

21 Q. Okay.

22 A. So, yeah.

23 Q. Okay, sir.

24   So that overlap of $84.8 million between the kickback

25 damages and off-label damages, that's what you're talking

United States District Court
District of New Jersey

 1   about?   There was a potential overlap of that amount.

 2   Is that right?

 3   A.   That's right.

 4   Q.   All right, sir.

 5   Now, if we look at that separately, you have kickback

 6   damages of $327.2 million, off-label damages of

 7   $361.9 million.

 8   Does that off-label damages amount of $361.9 million in

 9   damages to the government payors account for a reduction of

10   that overlap of 84.8 million?

11   A.   The 46-plus million minus the 84 I -- de-duplicated, it

12   means deducted basically the 84 from the 446.

13   Q.   So the 446.7 million in off-label damages, you deducted

14   the 84.8 million, and you arrive at 361.9 million for

15   off-label damages.

16   Is that right?

17   A.   That's correct.

18   Q.   And again, that was a reduction of 112,731 claims that

19   were submitted as well.

20   Right, sir?

21   A.   Yes.

22   Q.   Okay.

23   And it's approximately 19 percent for each reduction.

24   Do you see that?

25   A.   Correct.

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 1  Q.   All right.

 2        So now, Professor, we've got a de-duplication, and

 3  we've got a final slide for you this morning, kickback claims.

 4  Let me frame this by question.

 5        Okay, sir?

 6        Given your education, your training, your knowledge,

 7  and your experience, Professor Shaked, what is the total

 8  number of kickback claims that were submitted to government

 9  payors?

10  A.   327.2 million.

11  Q.   I'm sorry.  I apologize.

12        What were the total number of kickback --

13  A.   Oh, claims.

14  Q.   -- claims.  I apologize.  Let me frame it again.

15  A.   That's fine.  I got it.

16  Q.   Yeah.

17  A.   The number of claims, the kickback claims is 435,042.

18  Q.   And is that number of claims something that you've

19  assessed within a reasonable degree of certainty given your

20  knowledge, your training, your education, and your experience?

21  A.   Absolutely.  Otherwise I wouldn't present it here.

22  Q.   Okay.

23        How about with respect to kickback damages?  What was

24  the total number of kickback damages that you calculated

25  within a reasonable degree of certainty?
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United States District Court
District of New Jersey

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 1   A.   Talk about claims or damages?

 2   Q.   Damages, Professor.

 3   A.   Damages are 361.9 million.

 4   Q.   Sorry, Professor.  I'm asking about kickback damages.

 5   Let me sure I get this one by one.

 6        Okay, sir?

 7        What was the total number of kickback damages --

 8   A.   Oh.

 9   Q.   -- that you assessed within a reasonable degree of

10   certainty given your knowledge, your training, your education,

11   and your experience?

12   A.   It's 327.2 million.

13   Q.   Thank you.

14        Now, with respect to off-label claims, what is the

15   total number of off-label claims that you assessed associated

16   with off-label damages?

17   A.   481,265.

18   Q.   Sir, did you calculate that number of claims to a

19   reasonable degree of certainty, given your knowledge, your

20   training, your education, and your experience?

21   A.   Yes.

22   Q.   Finally, sir, with respect to off-label damages, what was

23   the total number of off-label damages to government payors

24   that you calculated?

25   A.   361.9 million.
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United States District Court
District of New Jersey

 1 Q.   And did you calculate that number to a reasonable degree

 2 of certainty given your knowledge, your training, your

 3 education, and your experience?

 4 A.   Yes.

 5 Q.   Professor Shaked, thank you, sir.

 6   MR. MARKETOS: No further questions.

 7   THE COURT: All right, thank you, Mr. Marketos.

 8   Ms. Brown?

 9   MS. BROWN: Thank you, Your Honor.

10   Your Honor, can I have the Court's permission to use a

11 board?

12   THE COURT: You may.

13   MS. BROWN: Thank you.

14   Your Honor, may we approach on one issue before I

15 begin?

16   THE COURT: You may.

17   MS. BROWN: Thank you.

18   (Sidebar begins at 11:17 a.m.)

19   MS. BROWN: I have one issue before we start.

20   THE COURT: Mr. Marketos?

21   MS. BROWN: Your Honor, we believe that there was

22 just an undisclosed expert opinion put up on the screen.

23   The number that was given in the errata, like the final

24 report, was 718 million, which is also the number they opened

25 on, but they just put different numbers up on the screen.

United States District Court
District of New Jersey

1   THE COURT: Which number are we talking about?

2   MS. BROWN: The damages number, so the total that

3   they give to put --

4   THE COURT: The total damages.

5   MS. BROWN: -- represents an undisclosed deduction.

6   We believe the final number in a disclosed report is

7   718 million and change, which is consistent with their opening

8   on 718.

9   THE COURT: What was the number that was shown?

10   MS. BROWN: Below 6, 680 maybe.

11   MR. MARKETOS: It was the de-duplication that he

12   attested to in his report.

13   THE COURT: Okay.

14   MS. BROWN: Okay. In the errata? Because this is

15   the number in the errata.

16   MR. MARKETOS: I don't know what you mean -- I'm

17   sorry. I don't know what you mean by errata.

18   THE COURT: I understand, but you didn't object at

19   the time. But if you want to raise it, you want me to deal

20   with it on a sidebar?

21   MS. BROWN: Well, I think -- I guess we'll just deal

22   with it on cross, or I mean, I don't know how --

23   MR. WYATT: The report itself, the de-duplication

24   number was 718, so it was --

25   MR. MARKETOS: So, sorry. I'm not following, and I

United States District Court
District of New Jersey

1   have to look at what they're talking about with the report,

2   but the testimony is consistent with his report.

3   And we have to project the damages based on

4   Your Honor's verdict sheet, and that's why it's separated in

5   kickbacks and in terms of off-label.

6   THE COURT: All right. Well, I don't have anything

7   else in -- for now I'm going to allow you to deal with it on

8   cross. If you think there's something more, you can raise it

9   at the end of the day.

10   MS. BROWN: Okay.

11   MR. MARKETOS: But they're saying it's lower --

12   MS. BROWN: Correct.

13   MR. MARKETOS: So their objection is it's lower.

14   MS. BROWN: Well, I mean, only because there is a

15   methodology, and now we have something different, but we can

16   spend the lunch break, Your Honor, trying to -- if your

17   representation is that was disclosed, then we'll --

18   MR. MARKETOS: I'm going to need to look at what

19   they're talking about, but so he's disclosed everything, so...

20   THE COURT: All right. So the number that he

21   testified to you don't believe is any different than what was

22   disclosed to Janssen sometime prior to his testimony.

23   MR. MARKETOS: No, I think that what they're talking

24   about --

25   THE COURT: Well, let's just leave it at that, then.

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 1  I don't want to get into it much more than that.  You guys

 2  tack it down later, and then let me know, but for now, let's

 3  go.

 4          MS. BROWN:  We will.  We'll do that.  Okay.  Thank

 5  you, Your Honor.

 6          (Sidebar was concluded at 11:19 a.m.)

 7          (Open court.)

 8          MS. BROWN:  May I proceed, Your Honor?

 9          THE COURT:  You may.

10          MS. BROWN:  Good morning, everyone.

11  (CROSS-EXAMINATION BY MS. BROWN:)

12  Q.   Good morning, Professor Shaked.  How are you?

13  A.   Thank you.  Good.

14  Q.   Good.

15       The truth is, Doctor, that CMS has reimbursed for many,

16  many prescriptions of Prezista and Intelence.

17       Correct, sir?

18  A.   Yes.

19  Q.   All right.

20       And, in fact, CMS is still, to this day, reimbursing

21  for those medicines.

22       Correct, sir?

23  A.   I assume so.  I don't know.

24  Q.   Okay.

25       And your damages model doesn't include all of the
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1   prescriptions that CMS has reimbursed for of these two

2   medicines.

3   Right, sir?

4   A.   Can you be more specific?

5   Q.   Sure.

6   A.   It does not include all -- what did I leave out, if you

7   tell me?

8   MS. BROWN: Can I have the ELMO, please, Mr. Morales.

9   BY MS. BROWN:

10 Q.   This is a slide you just showed our jury.

11   And you would agree that the government has reimbursed

12 for many more prescriptions of Prezista and Intelence than you

13 have included in your damages model.

14   Is that correct?

15 A.   That's correct.

16 Q.   Okay.

17   And your opinion, sir, about which Prezista and

18 Intelence prescriptions to include in your model depends on

19 who initiated the prescription.

20   Right, sir?

21 A.   That's correct.

22 Q.   Okay.

23   And the --

24 A.   In the off-label. In the off-label, not in the speaker.

25 Q.   Well, we'll talk about the speaker claims and the

1 promotional claims, okay?

2 A.   Okay. Yes.

3 Q.   Because you know for a speaker, it doesn't matter in your

4 model if the subsequent prescriptions were on label or off

5 label.

6   Right, sir?

7 A.   Correct.

8 Q.   You have included, once a speaker spoke for Janssen --

9 every single prescription that doctor wrote up until

10 December 31st, 2014, is included in your model.

11   Right, sir?

12 A.   That's correct.

13 Q.   All right.

14   What matters to you in terms of which prescriptions

15 you've included in your model is whether or not the

16 prescription is -- the doctor is influenced.

17   Right, sir?

18 A.   That's correct.

19 Q.   Okay.

20   And influenced, I want to talk about your definition of

21 influenced.

22   MS. BROWN: And, Your Honor, I've shared the

23 demonstratives with counsel, so...

24   THE COURT: All right.

25 BY MS. BROWN:

United States District Court
District of New Jersey

1 Q.   All right.

2   This, Professor Shaked, is how, for purposes of your

3 opinion in this case, you have described an influenced

4 physician.

5   Right, sir?

6 A.   That's correct.

7 Q.   All right.

8   So it would be a doctor who had one visit -- at least

9 one visit from a Janssen sales representative.

10   Right, sir?

11 A.   At least.

12 Q.   At least.

13   A doctor -- or a doctor who attended at least one

14 speaking event.

15   Correct?

16 A.   That's correct.

17 Q.   Or a doctor who spoke at a speaking event.

18   Correct?

19 A.   That's correct.

20 Q.   And this definition of a, quote, influenced physician, it

21 did not come from CMS or the government.

22   Correct?

23 A.   No. Government doesn't define the influence.

24 Q.   Correct.

25 A.   That's correct.

1   Q.   There is no document or statement that you rely on that

2   CMS says, We don't pay for prescriptions that were written by

3   any doctor who fits one of your definitions of influenced.

4   Right, Doctor?

5   A.   I cannot say right or not. I don't know what the

6   government said or not. I cannot agree, say there is no

7   document. What do I know?

8   Q.   Well --

9   A.   There is no document. I was -- that's the definition, I

10 agree. But as to the rest of that, I don't know.

11 Q.   Let's talk about what you were provided for your opinion.

12   Okay, sir?

13 A.   That's fair.

14 Q.   We can agree, for purposes of your opinion in this case,

15 you didn't rely on any document from CMS that says they don't

16 pay for prescriptions written by what you define to be an

17 influenced physician.

18   Right, sir?

19 A.   Correct. Nowhere in my report was it I rely manage -- on

20 the government for me to define "influenced." It's not

21 written anywhere in my report.

22 Q.   That is right, sir.

23   What is in your testimony and your report is that this

24 definition of an influenced physician was provided to you by

25 the lawyers for the Relators.

United States District Court
District of New Jersey

1   Correct, sir?

2   A.   Correct.

3   Q.   All right.

4   And what this means, Doctor, for purposes of your

5   opinion, is the following: It means that if we consider a

6   patient who has a prescription written by a non-influenced

7   prescriber, those prescriptions are not included in your

8   damages model.

9   Correct, sir?

10   A.   Initiated but non-influenced, you're right.

11   Q.   Okay.

12   But it's the very same prescription, either for lipids

13   or Intelence naive or Prezista naive, if that very same

14   prescription is initiated by someone that you have defined as

15   influenced, you have included that in your damages model.

16   Right, sir?

17   A.   Included and it made sense to me, correct.

18   Q.   Right.

19   So same prescription, depending on who is prescribing

20   it initially, depended on whether or not it makes it into your

21   model.

22   Right, sir?

23   A.   Absolutely.

24   Q.   All right.

25   And one of the things we know is that a number of

United States District Court
District of New Jersey

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 1  doctors who had absolutely nothing to do with Janssen

 2  prescribed these medicines in the four ways that you

 3  considered for your promotional damages.

 4      Right, sir?

 5  A.  Are you saying that there are non-influenced who also

 6  wrote off-label?  That's what you mean in plain English?

 7  Q.  Yes, sir.  In plain English.  Thank you.

 8  A.  The answer is yes.

 9  Q.  Yes.

10      So -- and I want to talk to you about what you've

11  defined as "off-label."  But we can agree there are four

12  different types of prescriptions that you have considered to

13  be off-label.

14      Right, sir?

15  A.  Yes.

16  Q.  And our jury's heard a lot about them.  That's Prezista

17  naive, lipids, Prezista lipids.

18      Right?

19  A.  Yes.

20  Q.  Intelence naive and Intelence once a day.

21      Right?

22  A.  That's correct.

23  Q.  And you and I can agree, because you had the data that

24  there are thousands of doctors who never saw anybody from

25  Janssen who prescribed Prezista and Intelence in one of those
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1   four, quote, off-label ways.

2   Right, sir?

3   A.   What you leave out, correct, but in a very small

4   proportion compared to the influenced.

5   Q.   And I want to talk to you about the proportion, and I

6   want to talk to you about your statistics.

7   But we can agree -- and I'll put it up here on this

8   slide -- that, actually, there were 3,600 doctors who wrote

9   almost 200,000 of those, quote --

10 A.   Excuse me. Can you let me read it? You're asking me

11 whether it's --

12 Q.   Of course, Doctor.

13 A.   -- correct. You want me to read it?

14 Q.   Yes, sir.

15 A.   You put it just in front of me. I have no idea what it

16 is.

17   Okay. Sorry.

18 Q.   No problem, sir.

19   This data comes from your report. We actually cited it

20 down here in the bottom. Exhibit 26 to your report. And

21 you're familiar with the data in your report, sir, that shows

22 doctors who had nothing to do with Janssen prescribing these

23 medicines in the four, quote, "off-label ways" you've

24 identified.

25   Right, sir?

United States District Court
District of New Jersey

1 A.   Yes.

2 Q.   All right.

3   And so what that means, sir, is that for the very same

4 four things, four areas of prescriptions, if the same

5 prescription was written by an influenced prescriber, it's in

6 your model; if it was a non-influenced prescriber, it is not.

7   Correct, sir?

8 A.   Was initiated by influence, yes.

9 Q.   Okay.

10 A.   Initiated were non-influenced, it's not. That's one we

11 said at least a few times. You're correct.

12 Q.   And one of the things your report gives us, sir, is

13 information on the number of prescriptions that were written

14 in these, quote, off-label categories.

15   Right, sir?

16 A.   Yes.

17 Q.   And you know that, actually, the top two prescribers of

18 off-label were non-influenced physicians.

19   Right, sir?

20 A.   I don't know, but it's -- it's -- it's not very much my

21 opinion, but I don't know it.

22 Q.   All right. Let's take a look.

23   This is also from Exhibit 26 to your report. And you

24 know, sir, that at 26 of your report, you can sort the

25 off-label prescriptions into terms of who wrote the most

1   amount of these four off-label prescriptions.

2   And the top two doctors who wrote the most off-label

3   prescriptions had nothing to do with Janssen. You know that.

4   Right, sir?

5   A.   A, I don't know. B, I would like to look at the data.

6   You put something in front of me, ask me I know. I

7   don't know. You pull up two numbers out of my report and say,

8   you know. No, I don't know.

9   Q.   Sir --

10   A.   Let me look at it.

11   Q.   Yes, sir.

12   This is Exhibit 26 to your report, sir.

13   A.   Fine. I don't know that.

14   Q.   Are you familiar with that?

15   A.   I don't know all the 26 exhibit in my -- already. Can I

16   look at it?

17   Q.   I will be happy to give you Exhibit 26, but what I want

18   you to do is take my word that I cut it correctly out of your

19   report.

20   Okay, sir? Do you see that there?

21   A.   I don't know what this is. I need a minute to comprehend

22   what I see in front of me. I don't know to be --

23   THE COURT: Doc, take a look at it. Just take a look

24   at it, and then wait for the question.

25   THE WITNESS: Fine.

United States District Court
District of New Jersey

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 1              MS. BROWN:  And, Your Honor, may I hand up the

 2   Exhibit 26 he's asking for?

 3              THE COURT:  You may.

 4              MS. BROWN:  Thank you.

 5   BY MS. BROWN:

 6   Q.   Professor, here is a little more detail about what we put

 7   on the slide.

 8        Doctor, let me know when you've had a chance, when

 9   you're done taking a look there.

10   A.   Okay.

11   Q.   Are you ready to proceed, sir?

12   A.   Yes.

13   Q.   I provided you with -- you see we cited on this slide

14   where we took the information, Exhibit 26 to your report, and

15   you agree that you can sort in Exhibit 26 the physicians or

16   the doctors who wrote the most amount of off-label

17   prescriptions.

18        Right, sir?

19   A.   That's fine.  Correct.

20   Q.   And you see that the top two off-label prescribers were

21   non-influenced physicians.

22        Right, sir?

23   A.   Correct.  I do statistics on -- 100,000 people, not on

24   two.

25   Q.   And, in fact, the total amount of off-label prescriptions
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United States District Court
District of New Jersey

1 that the top off-label prescriber wrote was 63 percent.

2   Right, sir?

3 A.   That's what it says, right.

4 Q.   And for the second one, it was 59 percent.

5   Correct, sir?

6 A.   Okay.

7 Q.   One of the things we know is that whatever motivated or

8 caused these two physicians to write these prescriptions for

9 their patients off-label, we know it wasn't Janssen.

10   Right?

11 A.   I am not sure what you say, "we know." What you know and

12 I know? Can you explain what I should know? You say, "we

13 know."

14 Q.   I'll ask a better question. How about that?

15 A.   That would be good.

16 Q.   One of the things we know is that these top two doctors

17 did not receive any sales visits or speaker engagements from

18 Janssen.

19   Correct?

20 A.   Correct. Non-influenced, correct.

21 Q.   All right.

22   And one of the things that you were here for last week

23 was Dr. Glatt's testimony.

24   Do you remember that, sir?

25 A.   Yes.

1   Q.   All right.

2   And Dr. Glatt actually talked about the reasons that

3   physicians like himself prescribe off-label.

4   Do you remember that, sir?

5   A.   Yes, I remember that.

6   Q.   And so, for example, Dr. Glatt said sometimes off-label

7   prescribing can be medically appropriate.

8   You recall sitting here for that testimony.

9   Right?

10   A.   Yes.

11   Q.   And, in fact, he said himself, as a prescriber of HIV

12   medicines, he's prescribed off-label many times.

13   Right, sir?

14   A.   I don't know many times, but I -- I know that he says

15   sometimes.

16   Q.   Do you recall his testimony that, many times in his

17   medical judgment, he had prescribed off-label?

18   A.   That's fine. I -- I don't argue with Dr. Glatt.

19   Whatever he say, he say.

20   Q.   And one of the things Dr. Glatt spoke about that you'll

21   recall because you were sitting here, sir, is that he told us

22   that prescribing Prezista with someone for a lipid condition

23   is not off-label.

24   Do you recall that?

25   A.   I don't recall, but I believe you. You don't have to

United States District Court
District of New Jersey

1 remind me. I believe you.

2 Q. All right.

3   Here's his testimony from when you were here.

4 "Prescribing Prezista for someone a with a lipid condition is

5 not off-label."

6   Do you remember that, sir?

7 A. Yes. I read it now. I don't remember.

8 Q. All right.

9   And he also said on that same score, sir, nothing in

10 the label says that this medicine, Prezista, cannot be used in

11 a person with a lipid condition. And he agreed. It doesn't

12 state that.

13   Right, sir?

14 A. I read what it says. I don't disagree with him. I

15 cannot -- I'm not a doctor here. I just can tell you how I

16 used analysis in 100,000 people, not on one doctor or one

17 patient. The rest of that, I don't know.

18 Q. Well, in terms of the only doctor, though, sir, that

19 you've referenced as informing your analysis in any way it's

20 actually Dr. Glatt.

21   Right, sir?

22 A. I remember Dr. Glatt saying "very infrequently," and you

23 say medically accepted. So your qualification of what

24 Dr. Glatt said is fine. I don't disagree with you. He said

25 it.

United States District Court
District of New Jersey

1 Q.   And respectfully, sir, that wasn't my question.

2   My question was the only doctor who informed your

3 opinion in any way was actually Dr. Aaron Glatt.

4   Right?

5 A.   Right. I talked to -- Dr. Glatt was a consult.

6 Q.   Right.

7   You didn't actually speak to him yourself, but you

8 relayed some messages to and from him through the lawyers.

9   Correct?

10 A.   Absolutely. Yes.

11 Q.   And it was actually the lawyers who told you to consider

12 somebody with a prior lipid condition who gets Prezista as an

13 off-label prescription.

14   Right, sir?

15 A.   Yes. That's an off-label prescription based on

16 Dr. Glatt, and I see there was somebody else, but I don't know

17 exactly.

18   But you're right.

19 Q.   But based on what Dr. Glatt told our jurors when he was

20 here under oath, sitting exactly where you are, he said it's

21 not off-label.

22   Do you recall that?

23 A.   I don't recall. I can elaborate. If you don't, I don't.

24 Q.   I'm sorry, sir?

25 A.   I say I can say something. I recall that. But if you

 1 don't want it, it's fine.

 2 Q.   Okay.

 3   Do you see the testimony here on the slide, sir?

 4 A.   I see the testimony. It's taken out of context.

 5 Q.   And you were, in fact, in the courtroom the day he was

 6 testifying.

 7   Right, sir?

 8 A.   As I say, it's taken out of context.

 9 Q.   And, in fact, the decision -- when you showed your

10 damages slide, actually, sir, I did want to ask you something

11 about that.

12   As it relates to this lipid claims, actually, it's by

13 far the largest amount of damages on this slide.

14   Right, sir?

15 A.   Makes sense because one out of every two patients of HIV

16 have high cholesterol.

17 Q.   Yeah.

18   Because having HIV actually can impact a patient's

19 lipids. You know that.

20   Right, sir?

21 A.   I just say that your expert say himself in his report

22 that half of the people that have HIV -- sorry -- with HIV

23 have lipid problems. So last thing you want is to keep

24 pushing it up.

25 Q.   So, sir, my question was, if you look at this slide that

1 you showed our jury, the largest circle of damages by far are

2 the lipid claims.

3   Right, sir?

4 A.   That's right. Yes. Yes.

5 Q.   And all of the parameters for identifying a lipid claim

6 or considering a lipid claim to be, quote, off-label, those

7 parameters were given to you by the lawyers.

8   Correct, sir?

9 A.   By the lawyers in consultation with the doctors.

10 Q.   And the doctor is in consultation with Dr. Glatt.

11   Right, sir?

12 A.   That's right.

13 Q.   All right.

14   Our jury has seen this slide, sir, quite a bit during

15 our trial. And I want to ask you a couple of things about it.

16   You understand that the claims that you just tallied up

17 for our jurors were submitted to CMS by something called Plan

18 D sponsors.

19   Right, sir?

20 A.   That's correct.

21 Q.   You understand that's how a claim gets to the government

22 for reimbursement.

23 A.   I don't know all that -- all that, you know, flow, but I

24 know of Part D sponsors.

25 Q.   All right.

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 1        And as it relates to the claims that you identified in
 2   your PowerPoint presentation, you don't know how many Plan D
 3   sponsors submitted those claims to the government.
 4        Correct?
 5   A.   Should have asked it last week to Ian, too.  That's a
 6   data question.  I don't know.
 7   Q.   Right.
 8        I'm just asking you --
 9   A.   I don't know the answer to that.
10   Q.   -- to answer -- all right.
11        And you don't know how each of those individual Plan D
12   sponsors evaluated whether or not the claim was reimbursable
13   by CMS.
14        True?
15   A.   I don't know those details, no.
16   Q.   Okay.
17        What you did for purposes of your model, sir, is you
18   assumed that Plan D sponsors submitted claims to the
19   government that should not have been reimbursed.
20        Correct?
21   A.   I don't know that, that statement that I did not assume.
22        I assumed that claims were submitted and eventually
23   were reimbursed by the government.  Whether it was something
24   irregular or illegal in the middle, I am not here to opine on
25   it, and it's in neither one of my reports.
```

1   Q.   In fact, sir, you're not here to offer any opinion, even

2   for the claims in your damages model, about whether or not the

3   government would have or should have reimbursed for those

4   claims.

5   Correct?

6   A.   I know that the claims were submitted and paid. They

7   should or would. I am not here for the -- representing the

8   U.S. government.

9   Q.   You, sir, have identified a certain number of claims

10   pursuant to direction from the lawyers.

11   Correct?

12   A.   I am not sure exactly what you're saying.

13   Q.   Well, in terms of whether or not -- you understand part

14   of what our jury is going to openly decide is if CMS should

15   have paid for these prescriptions.

16   Do you understand that, generally?

17   A.   My understanding is that truly understand that the

18   government paid.

19   Q.   Yes, sir.

20   A.   So it went out of the pocket of the government to

21   Janssen. The rest of that, I don't know.

22   Q.   Right.

23   And in terms of whether or not it was proper for the

24   government to reimburse for the claims that you identified in

25   your PowerPoint, you are not offering an opinion on that

     1   subject.

     2   Correct?

     3   A.   Whether the government should pay?

     4   Q.   Correct.

     5   A.   No. I just say -- I located the amount the government

     6   actually paid.

     7   Q.   Yes, sir.

     8   A.   Whether they should or not, that's not my opinion.

     9   Q.   All right.

    10   One thing you would agree with, though, sir, is that

    11   every claim that you identified was a claim for an HIV

    12   medicine prescribed to an HIV patient.

    13   Right, sir?

    14   A.   I assume so. I did not check every one of them, but in

    15   the database, people were, based on coding, identified as

    16   having HIV.

    17   Q.   Yes, sir.

    18   And you don't dispute, Professor Shaked, that our

    19   national strategy in this country is to give HIV patients

    20   unfettered access to the HIV medicines they need to stay

    21   alive.

    22   Right, sir?

    23   A.   I'm not here to opine on national strategy. I'm sorry.

    24   Q.   Well, in terms of --

    25   A.   I cannot tell you "yes" or "no." You ask me, do you

United States District Court
District of New Jersey

 1   know. I don't know national study. I have no field for that.

 2   Q.   All right. Let me see if I can show it to you, then.

 3   MS. BROWN: Your Honor, it's tab 33, D-3005.

 4   Permission to admit and display.

 5   MR. MARKETOS: No objection.

 6   THE COURT: All right. So admitted.

 7   (Defendants' Exhibit D-3005 in evidence.)

 8   BY MS. BROWN:

 9   Q.   Sir, in connection with your work on the case, were you

10   provided with and did you review the national strategy on HIV

11   and AIDS for the United States that was in effect during the

12   time period that you looked at claims?

13   A.   Might be the case. I don't recollect.

14   Q.   All right.

15   Let's take a look at Vision for the National Strategy

16   on page 3 of this government document.

17   Did you know, sir, that the Vision for the National HIV

18   Strategy during this relevant time period was as follows:

19   That the United States would be a place where merely

20   HIV infections are rare, and when they do occur, every person,

21   regardless of age, gender, race, ethnicity, sexual

22   orientation, gender identity or socioeconomic circumstance,

23   will have unfettered access to high-quality, life-extending

24   care, free from stigma and discrimination.

25   Did you know that, sir, when you created your

1 PowerPoint in this case?

2 A.   I don't know that one. I just know the government also

3 say do not promote -- promoting off-label. So that's not

4 written here.

5 Q.   And you know the government has also identified

6 antiretroviral medicines like Prezista and Intelence in a

7 protected class of medicines.

8   Right, sir?

9 A.   I -- I read something about it, but it doesn't -- it does

10 not affect my opinion. My opinion is very simple.

11 Q.   And you know, and our jury's already seen a document

12 about it, that the government, at least the federal

13 government, does not permit utilization tools to be used by

14 Plan D sponsors to limit access to these medicines.

15   Do you know that, sir?

16 A.   No. The only thing I know, you're not supposed to

17 promote off-label. And if you collect it, you have to return

18 the money. That's all I know from my report.

19 Q.   And in terms -- on that score, sir, in terms of this

20 opinion that you're giving about off-label, you have been

21 instructed to assume that Janssen did, in fact, promote these

22 medicines off-label.

23   Correct, sir?

24 A.   I was requested to assume. And, in my opinion, it's

25 corroborated by the evidence and my statistics.

```
 1   Q.   And the evidence, sir, that you're referring to would be

 2   the handful of depositions that you identified for us earlier.

 3        Correct, sir?

 4   A.   And my statistics.  What I showed today clearly show that

 5   there is a relationship.

 6   Q.   Well, we're going to talk about that.

 7        But I'm talking about now just the assumption you made

 8   that Janssen did, in fact, promote off-label.  That is

 9   something you were instructed to do by the lawyers who hired

10   you.

11        Correct, sir?

12   A.   That's correct.

13   Q.   All right.

14        And I want to go into some of the other assumptions

15   that you made for your model, okay, sir, and talk a little bit

16   about them.

17   A.   Sure.

18   Q.   All right.

19        One of the things we can agree on, though, is that your

20   damages model, like all damages models, are based on certain

21   assumptions.

22        Correct?

23   A.   Every model based on some assumptions.

24   Q.   Correct.

25        And one of the things that you've written about before,
```

 1 sir, is that, if assumptions are unreasonable, the whole model

 2 becomes unreliable.

 3   Right?

 4 A.   I don't disagree with that one, but I have no

 5 unreasonable assumption in my model.

 6 Q.   You don't disagree with it, Professor Shaked --

 7 A.   No.

 8 Q.   -- because you've written that --

 9 A.   I say I don't disagree, but I say that my model doesn't

10 have any unreasonable. It's not relevant to my model. Not in

11 this case.

12 Q.   Let's talk a little bit about some of the things that you

13 assumed in this case for your model.

14   Okay, sir?

15 A.   Okay.

16 Q.   One of the things that you assumed was that every single

17 sales call contained an off-label message for both Prezista

18 and Intelence.

19   Right, sir?

20 A.   That's correct.

21 Q.   All right.

22   And you know that the testimony -- first of all, you

23 know that there's been a lot of testimony that's come before

24 our jury in the last month.

25   Right?

```
 1  A.   Right.

 2  Q.   You've been here for some of it.

 3       Right?

 4  A.   Correct.

 5  Q.   And you know that there is not a single witness who has

 6  testified consistent with the assumption that you made, that

 7  every single sales call involved an off-label message for

 8  Prezista and Intelence.

 9       Do you know that, sir?

10  A.   I don't know it.

11  Q.   All right.

12       I want to talk to you about some of the testimony our

13  jury has heard, including during the time period that you've

14  been sitting in this courtroom.

15       Okay, sir?

16       MS. BROWN:  And to do that I want to use this board,

17  with the Court's permission.

18  BY MS. BROWN:

19  Q.   So I want to go through and try to put up on our board

20  the assumption that you made and what folks have testified to

21  on that score.

22       Okay, sir?

23  A.   As long as you promise me to show everything that was

24  testified on this subject, not select --

25  Q.   Absolutely, sir.
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1 A.   -- out of context.

2 Q.   All right.

3   So we have -- I put everybody's picture on a magnet.

4 We have you, sir, over here, and your assumption is

5 100 percent of sales calls involved off-label messages for

6 Prezista and Intelence.

7   Right?

8 A.   That's correct.

9 Q.   All right.

10   Let's talk about the testimony, though, that we've

11 actually heard from witnesses in this case on that very

12 subject.

13   So one of the things you know, of course, is that

14 Dr. Ricky Hsu is a doctor we called out of turn in the other

15 side's case.

16   Right, sir?

17 A.   He's influence, right?

18 Q.   He was on our speaker bureau. He is the medical director

19 of the largest AIDS nonprofit in the entire world.

20   You heard that testimony.

21   Right, sir?

22 A.   That's correct.

23 Q.   All right.

24   And you heard Dr. Hsu testify that sales -- Janssen

25 sales representatives did not promote to him off label.

United States District Court
District of New Jersey

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 1        Right, sir?

 2  A.    He can say whatever he wants.  I cannot disagree with

 3  him, but I don't know.  That's fine.

 4  Q.    You were here when he testified.

 5        Right, sir?

 6  A.    Yeah.

 7  Q.    All right.

 8        Dr. Hsu testified inconsistent with the assumption that

 9  you made.

10        Agree?

11  A.    I disagree because you got 1,040 calls and not every one

12  of them were about the New York Yankees.

13  Q.    Sir, I want to talk to you about the testimony under oath

14  that Dr. Hsu, the medical director of the AIDS Foundation,

15  gave in our court.

16        Okay?

17  A.    You can -- you can bring it up.

18  Q.    Sure.

19        And what Dr. Hsu testified is that he does not believe

20  that Janssen sales reps promoted to him off label.

21        Right, sir?

22  A.    I don't know what his relationship is.  I cannot --

23  cannot testify what he is.  I just tell you what I know.

24  Q.    Okay.

25        What you know was what he testified to while you were
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1 sitting here.

2   Right, sir?

3 A.   I heard it from at least 10, 15 other people,

4 differences.

5 Q.   Okay.

6   Let's talk about some other testimony that has come

7 into this courtroom on this score.

8   We actually heard in this trial a secret recording that

9 Ms. Brancaccio made of a sales visit with Dr. Turrett.

10   Did the lawyers give you that in connection with your

11 opinion, sir?

12 A.   I -- I know what -- I -- I read the transcript of it.

13 Q.   Okay.

14   You read the transcript of the day in court when we

15 played part of the recording from Dr. Turrett?

16 A.   I heard all the transcript of all the trial every day.

17 Q.   You read everything that's happened in the whole trial.

18   Is that right, sir?

19 A.   That's correct.

20   MR. MARKETOS: I apologize for interrupting, Judge.

21 This has nothing to with this examination. We received some

22 notification that we need to notify you about something

23 related to the building.

24   THE COURT: Yeah. Sidebar.

25   (Sidebar begins at 11:50 a.m.)

United States District Court
District of New Jersey

 1   MR. MARKETOS: Somebody said that there's -- sorry

 2   about this.

 3   THE COURT: This is what is going on. So the U.S.

 4   Marshals, they haven't evacuated the building yet. There is a

 5   suspicious package in the building.

 6   But the reason why it's come up is they're not --

 7   they're preventing anyone from coming in, but they haven't

 8   evacuated us.

 9   So I'm trying to get information from the Marshal

10   Service right now, which is why I didn't make an announcement.

11   Are you hearing the same thing?

12   MR. MARKETOS: Oh, yes. They just said, Please let

13   the judge know in case he hasn't heard.

14   THE COURT: Yeah. I'm waiting for the marshals to

15   give me some direct feedback. We may have to evacuate, or it

16   may delay your lunch to be extended because if we break for

17   lunch -- I don't know the thinking behind not allowing people

18   in but not allowing us out, but there's probably a good reason

19   why they haven't ordered an evacuation of the building.

20   So I'm not concerned about that, but I am trying to get

21   additional information. If I think after I get the

22   information that we need to evacuate, even if the marshals

23   don't direct it, I will.

24   But I don't have that information yet, and a suspicious

25   package in this building can be computer equipment for the IT

  1 department, which happens from time to time.

  2   So before I call us quits where we have to leave the

  3 building and we may not be able to get back in for two hours,

  4 depending on when they get a K9 and all that, I'm going to

  5 play it by ear.

  6   What's the second issue?

  7   MR. MARKETOS: No, that was the issue.

  8   THE COURT: I appreciate it.

  9   MR. MARKETOS: Because our folks with the lunch can't

 10 get in.

 11   THE COURT: Are they blocked? Yep.

 12   MR. MARKETOS: Yes.

 13   THE COURT: Yeah. So what I'm going to do is if

 14 lunch gets impacted, we're going to have to have a longer

 15 lunch, but I don't know yet, and I'm waiting for the marshals

 16 to give me some direct info because that's all I've got.

 17   MR. MARKETOS: Okay. Sorry about that.

 18   THE COURT: No, no. That's okay. Do you want me to

 19 say something to the jurors?

 20   MS. BROWN: No.

 21   THE COURT: I mean, I don't want -- I don't like --

 22 the reason why I don't bring it up, I think it panics people

 23 before I know the info.

 24   MS. BROWN: Yeah, I agree with that.

 25   THE COURT: All right. So let's continue. Okay.

United States District Court
District of New Jersey

1   (Sidebar was concluded at 11:52 a.m.)

2   (Open court.)

3   MS. BROWN: May I proceed, Your Honor.

4   THE COURT: You may.

5   BY MS. BROWN:

6   Q.   When we left off, sir, we were talking about Dr. Turrett

7   and the secret tape recording that we listened to in court,

8   and you remember that.

9   Right, sir?

10   A.   Yes.

11   Q.   And you remember that on that recording, Dr. Turrett

12   talked about all of the reasons why he prescribes medicines

13   for his HIV patients.

14   Right, sir?

15   A.   Yeah. Might well be the case. I don't remember all the

16   detail.

17   Q.   Okay.

18   And even though you have assumed, sir, that 100 percent

19   of every single sales call involved an off-label message for

20   Prezista and Intelence, you know that even Ms. Brancaccio

21   agreed that on that call with Dr. Turrett, they didn't even

22   talk to him about any Intelence message.

23   Do you remember that being Ms. Brancaccio's testimony?

24   A.   Yes.

25   Q.   All right.

United States District Court
District of New Jersey

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 1         And if we look at testimony, Slide 9, we can see what

 2   Ms. Brancaccio testified to down here at the bottom.

 3         You knew that the evidence on this tape showed just the

 4   opposite of any effort to detail or talk to Dr. Turrett about

 5   any Intelence message, much less an off-label Intelence

 6   message.

 7         You know that that was her testimony, which is

 8   inconsistent with the assumption you made in this case.

 9         Right, sir?

10   A.   I don't think it's inconsistent.  This is two lines from

11   her.  She has a 400 page deposition that you don't show me,

12   and at her deposition, she talks about off-label.  So giving

13   me five lines and saying, It's this, it's -- it contradicts my

14   testimony, that's really not appropriate.

15   Q.   Let's talk about the testimony that came in in this

16   trial.

17         Are you with me, sir?

18   A.   Yes.

19   Q.   All right.

20         In this trial you have assumed that every single sales

21   visit involves off-label messages for both Prezista and

22   Intelence.

23         Right, sir?

24   A.   That's right.

25   Q.   That's right.
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United States District Court
District of New Jersey

1   A.   It's not right, because the first one, Intelence was not

2   even there.

3   Q.   Sure.

4   Once Intelence was approved.

5   Right, sir?

6   A.   That's correct.

7   Q.   All right.

8   And we heard testimony from Dr. Turrett that was

9   secretly recorded from Ms. Brancaccio; you know that, sir,

10   because you read everything in this trial.

11   Right?

12   A.   That's right.

13   Q.   And Ms. Brancaccio agreed with what our jurors heard,

14   which was that there wasn't a single Intelence message given

15   by Ms. Brancaccio on that entire tape.

16   You know that.

17   Right?

18   A.   Yes.

19   Q.   And you know that Dr. Sillup, he testified -- were you

20   here for that, sir, when Dr. Sillup testified?

21   A.   No.

22   Q.   All right.

23   Did you read his testimony --

24   A.   Yeah.

25   Q.   -- as part of your work in the case?

1   A.   Yes.

2   Q.   And you know that Dr. Sillup testified that if -- it

3   wouldn't even make sense that multiple messages were given

4   during the same sales call.

5   Do you recall that, sir?

6   A.   Can you repeat the -- multiple messages were given when?

7   Q.   Yes. Dr. Sillup --

8   A.   I couldn't -- I couldn't understand the sentence.

9   Q.   I understand.

10   Dr. Sillup testified about whether or not it's

11   reasonable to assume that multiple off-label sales messages

12   were given during one sales visit.

13   Do you remember that, sir?

14   A.   I don't remember this one, but I read his testimony, yes.

15   Q.   Sure.

16   I asked Dr. Sillup: "Is it fair to say that all four

17   of those messages would have been given in one call?"

18   And Dr. Sillup said, "that's not fair." He can't

19   imagine that happening.

20   Right, sir?

21   A.   Yes. I don't say that every call is all four messages.

22   That's not -- that's not written. I said that every call is

23   considered to be off-label promotion. I didn't say off of --

24   every call is four messages.

25   Q.   Every call, sir, you have assumed contained an off-label

 1 | message for Prezista and Intelence.

 2 | Right, sir?

 3 | A.   Correct, not to say all four.

 4 | Q.   And during a certain time period when all four of those

 5 | messages in the theory of the case could have been given, you

 6 | assume that they may all have been given at that time?

 7 | A.   Might as well be the case.

 8 | Q.   Yes.

 9 | And Dr. Sillup disagreed with your assumption that that

10 | was even a fair thing to assume.

11 | Do you know that, sir? Dr. Sillup said, "four messages

12 | in one call doesn't really make sense."

13 | Right, sir?

14 | A.   That's fine.

15 | Q.   And while you have assumed, sir, for purposes of your

16 | model that every single time one of the witnesses who

17 | testified in this court went on a sales call they delivered

18 | off-label messages, the testimony from the actual witnesses

19 | has been different.

20 | Right, sir?

21 | A.   Not necessarily. You don't bring here that I heard that

22 | somebody said at least 70 or 80 percent of the call. You

23 | don't say way more than 50 percent. You left out -- obviously

24 | you like to, you know, cherry-pick -- cherry-pick.

25 | Q.   Let's talk about what the actual evidence shows and not

1   about cherry-picking.

2   Okay, sir?

3   A.   About what?

4   Q.   I don't want to talk about cherry-picking. I want to

5   talk about the truth of the evidence that came in from that

6   witness stand.

7   Okay, sir?

8   A.   That's fine.

9   Q.   All right.

10   So you have assumed that every single time

11   Ms. Brancaccio went on a sales call, she delivered two

12   messages, at least one for Prezista and one for Intelence, and

13   she said it wasn't every time. You know that.

14   Right, sir?

15   A.   It's not exactly, because PILM say that if you talk about

16   Prezista, you also affect Intelence.

17   Q.   Sir, I'm talking about what the witnesses who came into

18   this court testified to. Ms. Brancaccio brought this lawsuit

19   and testified that there were certain providers she did not

20   give an off-label message to.

21   Right, sir?

22   A.   Yes.

23   Q.   She testified that sometimes when she went to a doctor's

24   office, she couldn't even see the doctor.

25   Right, sir?

United States District Court
District of New Jersey

1   A.   Yeah, might as well be the case. I don't remember that,

2   but I assume it's correct.

3   Q.   And she testified that it was not every single time that

4   she delivered an off-label message like you have assumed.

5   Right, sir?

6   A.   That -- that's correct.

7   Q.   Ms. Penelow also testified in this case, and she

8   testified similarly, that it was not every single time

9   delivering at least two off-label messages.

10   You know that.

11   Right, sir?

12   A.   Yes.

13   Q.   You know that Ms. Penelow, in fact, testified for all of

14   2006 she didn't deliver an off-label message at all.

15   You know that testimony?

16   A.   I don't remember, but it might as well be the case. I

17   don't -- I don't disagree with you on any one of the

18   testimonies.

19   Q.   So when you did all of that mathematical calculation that

20   you showed our jury, you didn't back out, for example, all of

21   the doctors that Ms. Penelow visited in 2006 where she said

22   she wasn't delivering any kind of off-label message.

23   Right, sir?

24   A.   I -- the answer is no. I don't want to elaborate. I'm

25   not going to sound argumentative.

1   Q.   Ms. Penelow testified about at least one colleague, Mr.

2   Steve Somacia, who she says didn't deliver off-label messages

3   at all. And in your model you didn't go in there and pull out

4   all the providers that Mr. Somacia visited and take them out

5   of your damages model.

6   Right, sir?

7   A.   I didn't take out anyone, including the person you say.

8   Q.   Right.

9   A.   I included all the people based on the criteria that I

10   told you, and it's definitely there. It's in my report. I

11   don't disagree with you about certain testimony about this.

12   But as I say, you're very careful not to show me

13   testimony that people say it's almost 100 percent.

14   Q.   I'm going to show you all the testimony that came in in

15   this court, I promise you, all of it. You read it. We saw

16   it. Our jury heard it, and I'm putting it up on the board.

17   Okay?

18   A.   Take your time.

19   Q.   And Ms. Penelow also said there were particular doctors

20   to whom she did not deliver an off-label message, and she

21   listed those doctors, but you didn't go into your model and

22   pull out her visits to those doctors when you were doing all

23   the math that you showed our jury about this morning.

24   Right, sir?

25   A.   That's correct.

United States District Court
District of New Jersey

1   Q.   We heard from Donna Graham talking about -- making sure

2   that we get everybody who testified. She was the first

3   witness in the case.

4   And one of the things you know is that she testified as

5   to one of the four off-label uses, Intelence in

6   treatment-naive patients -- she testified she never promoted

7   that way and she never heard of anybody promoting Intelence in

8   treatment-naive.

9   Do you remember that, sir?

10 A.   I believe I remember, yeah.

11 Q.   Right.

12   So if we look at what the very first witness in the

13 case said, we asked Ms. Graham, in terms of Relators' claims

14 in the lawsuit, that from 2006 -- it actually was 2014 there

15 was an instruction to promote Intelence in treatment-naive.

16 "For your period of time at Janssen, you never heard of that?"

17   "I don't recall that. I don't remember the direction

18 around that. I don't remember speaking about it in

19 treatment-naive patients."

20   Well, you assumed that those messages were being given

21 every single time a sales representative met with a doctor.

22   The testimony from the very first witness, at least as

23 to Intelence and treatment-naive, is that she had no memory of

24 that.

25   Right, sir?

1 A.   That's fine. I read it, yeah.

2 Q.   Mr. Holshoe, he was in here last week, sir, and he said

3 he has no memory of delivering the message that Prezista is

4 lipid friendly.

5   Do you remember that, sir?

6 A.   Yeah. I remember.

7 Q.   And do you remember that as it relates to off-label

8 discussions with physicians, Mr. Holshoe's testimony was that

9 he did not deliver off-label messages every time?

10   Do you remember that testimony, sir?

11 A.   I don't remember, but I have seen enough documents using

12 the word lipid neutral and lipid friendly.

13 Q.   I'm just talking about the testimony that came into our

14 jury from the witness stand.

15   You with me, sir?

16 A.   Yeah. I don't remember these details of Mr. Holshoe.

17 Q.   Remember Mr. Holshoe? You were here for that, or you

18 read it.

19   Right, sir?

20 A.   What is that? Sorry.

21 Q.   You --

22 A.   No, I was not here when he testified.

23 Q.   You read his testimony?

24 A.   Yeah. I read it.

25 Q.   All right.

United States District Court
District of New Jersey

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 1        And you know that as to this idea about telling a

 2   physician Prezista was lipid friendly, he has no memory of

 3   that.

 4        Right, sir?

 5   A.   That might be the case.  I don't remember.

 6   Q.   All right.

 7        And whether he discussed it, you assumed he -- that

 8   every sales rep, every time delivered two off-label messages,

 9   and at least Mr. Holshoe, one of the witnesses the Relators

10   brought in here, he said no, he did not do that.

11        You see that testimony, sir?

12   A.   I see the testimony, but I don't disagree with what

13   somebody said.  I just say that --

14             THE COURT:  Sir?

15             THE WITNESS:  I got it.

16             THE COURT:  I know you said you don't want to be

17   argumentative, but now I'm going to intervene.

18             THE WITNESS:  Yeah.

19             THE COURT:  I need you to just answer the questions

20   that are posed to you.  Do you understand that, Professor?

21             THE WITNESS:  Yeah.  Yeah.  Thank you.  Thank you,

22   Your Honor.

23   BY MS. BROWN:

24   Q.   Matt Grooms was another witness that the Relators brought

25   in here.
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 1        And you know, sir, that he testified as to Prezista
 2  treatment-naive, that is not a message that he delivered.
 3        Right, sir?
 4  A.   As I said, might as well be the case.  I don't remember
 5  all the testimonies, but I believe you.
 6  Q.   All right.
 7        Sales reps around the country, did they tell you they
 8  were promoting -- this is one of your four off-label
 9  messages -- Prezista for treatment-naive patients?
10        He has no memory of that.
11        Right, sir?
12  A.   Yes.
13  Q.   All right.
14        And you didn't go into the database and try and back
15  out doctors that he visited where you were assuming this
16  message was delivered.
17        Right, sir?
18  A.   I didn't take out, no.
19  Q.   Mr. Wilhelm, Ms. Strand, they came in here, and they
20  testified that nobody ever gave them verbal instructions to
21  promote off label?
22  A.   Who is that?  Sorry.
23  Q.   Mr. Wilhelm?
24  A.   Wilhelm.
25  Q.   Yep.
```

United States District Court
District of New Jersey

1   Remember him?

2   A.   Mark Wilhelm, yeah.

3   Q.   Yes.

4   And Sara Strand, do you remember her?

5   A.   Yes.

6   Q.   And you know that the testimony from both of those

7   witnesses was that they never received verbal or written

8   instruction to do what you've assumed here, which is to go on

9   every sales visit and promote off label.

10   Do you remember that, sir?

11   A.   I don't remember this specific. I remember many other

12   things that Mark Wilhelm say.

13   Q.   And you know because you spoke about it on your direct

14   examination, sir, that the total amount of sales visits that

15   you looked at in this case were almost 700,000.

16   Right, sir?

17   A.   620,000.

18   Q.   620. And by my count I think it was even a little more.

19   696.

20   Do you know that, sir?

21   A.   Oh, you counted more?

22   Q.   I counted a little more.

23   A.   Okay.

24   Q.   All right.

25   Somewhere in the six hundred thousands. Can we agree

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 1   on that?

 2   A.   Yes.

 3   Q.   All right.

 4        And you know, because you heard the testimony, that the

 5   physicians to whom these 600,000 visits were made had an

 6   obligation under the FDA regulations to report if any sales

 7   representative was in their office promoting off label.

 8        You know that.

 9        Right, sir?

10   A.   Right, correct.

11   Q.   And you weren't provided any evidence in this case that a

12   single physician ever reported or called with a concern that a

13   Janssen's sales representative was in their office promoting

14   off-label in the way you have assumed for your entire damages

15   model.

16        Right, sir?

17   A.   I don't know of any, neither way.

18   Q.   You never spoke to any of the physicians who are at issue

19   in your damages model.

20        Correct, sir?

21   A.   I never spoke to any one of the physicians, correct.

22   Q.   You were never provided a sworn declaration or any kind

23   of sworn statement from any physician in your model that

24   substantiates the assumption you made that, every single time

25   a Janssen sales rep met with a physician, they delivered at
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1 least two off-label messages.

2   Right?

3 A.   Correct.

4 Q.   You're not aware of a single physician who will testify

5 for the Relators that the things they told you to assume for

6 your work in this case actually happened.

7   Right?

8 A.   I -- I didn't ask people to come.

9 Q.   They didn't show you any doctor.

10   Right?

11 A.   I -- I don't know.

12 Q.   When you sat back here watching the trial, you didn't see

13 a single doctor testify for them that any of what they've

14 claimed in this lawsuit for which you've put damages at nearly

15 $700 million -- nobody came in here to say that's true.

16   Right, sir?

17 A.   If I got a million dollars like Dr. Hsu, I also would not

18 show up.

19 Q.   Sir, you would testify incorrectly for a million dollars?

20   Is that what you said?

21 A.   I didn't say that. I said I will not show up.

22 Q.   I want to talk to you, sir, about some of the speaker

23 programs that you spoke about.

24   Okay, sir?

25 A.   Which program?

United States District Court
District of New Jersey

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 1  Q.   Speaker program.

 2  A.   Speaker program, yes.

 3  Q.   All right.

 4       Let's talk about how you calculate damages for

 5  speakers.

 6       Okay, sir?

 7       Your definition of an influenced physician means every

 8  time a speaker spoke or a doctor attended an event, they're

 9  influenced.

10       Right?

11  A.   That's correct.

12  Q.   All right.

13       And you know that many of the speaking events that

14  Janssen held were something called "Disease Awareness Events."

15       Do you know that, sir?

16  A.   I don't know what proportion.  I have the word "Disease

17  Events."

18  Q.   All right.

19       Were you here when we showed the chart to Ms. Evans

20  that there were almost 2,000 disease awareness speaking

21  events?

22  A.   No.

23  Q.   Do you know that, at a disease awareness speaking event,

24  the speaker doesn't mention the name of any medicine.

25       Do you know that, sir?
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 1 A.   I don't know what might be the case.

 2 Q.   All right.

 3   Do you know that at those disease awareness events, the

 4 topics are things like HIV and aging, HIV and depression,

 5 general topics about the disease state?

 6   Do you understand that, sir?

 7 A.   I -- I cannot tell you. I haven't been at any one of

 8 these events.

 9 Q.   You didn't look at any of the presentations that were

10 given at those events.

11   Fair enough, sir?

12 A.   Not in this one. There was 7- or 9,000 events, and this

13 might be 2,000 of them. I don't know about them.

14 Q.   In fact, though, you haven't looked at any of the speaker

15 decks for any of the speaker programs that were given over

16 this time period.

17   Right, sir?

18 A.   No. I was not given that one --

19 Q.   Right.

20 A.   -- because I know that there was also a backup slides

21 that were not published.

22 Q.   Well, sir, you know that because the lawyers told you

23 that.

24   Right, sir?

25 A.   No. Because I've seen testimony. I read lots of

1 deposition before coming here.

2 Q.   Yep.

3   You didn't look at any of the documents that, for

4 example, Ms. Brancaccio claims had backup slides.

5   Right, sir?

6 A.   I don't remember seeing.

7 Q.   Do you know how many presentations in total in the entire

8 case have been identified as having backup slides?

9 A.   I -- no, I don't know.

10 Q.   Do you know where the one presentation that was

11 identified as having backup slides was found?

12 A.   I don't know. I read for more than one person about this

13 backup slides.

14 Q.   Despite the fact that you never looked at what any of

15 those speaker decks contained, you claim that any time a

16 speaker spoke, any prescription that he or she wrote for the

17 end of time, at least until 2014, should not have been

18 reimbursed by the government.

19   Correct, sir?

20 A.   That's correct.

21 Q.   And that doesn't matter whether the speaker wrote an

22 on-label prescription or an off-label prescription.

23   Correct?

24 A.   That's right. That's the nature of kick- -- as far as I

25 know --

1 Q.   And you're not aware --

2 A.   -- the kickback case.

3 Q.   I apologize, sir.

4   You're not aware of any statement from CMS that they do

5 not reimburse for prescriptions that are written by doctors

6 who served as a speaker for a pharmaceutical company.

7   Correct, sir?

8 A.   Correct. I am sure the government is not happy if you

9 promote off-label, but your statement is correct.

10 Q.   One of the other things you have assumed, sir, is that

11 not only was an off-label message delivered 100 percent of the

12 time, but that the doctor was influenced by that off-label

13 message 100 percent of the time.

14 A.   I don't the 100 percent, but my statistics show that they

15 were influenced and they made -- it made a difference.

16 Q.   Okay.

17   That wasn't my question, though, sir. And my

18 question -- and let me show you something and see if we can

19 agree -- has something to do with the assumptions that you

20 made in the case.

21   Okay, sir?

22   And one of the things that you have assumed -- we

23 already talked about your assumption that the sales reps were

24 delivering off-label messages 100 percent of the time.

25   Right, sir?

United States District Court
District of New Jersey

1 A.   Yes.

2 Q.   We spoke about that.

3   But you also assumed that the doctor wrote a

4 prescription because of what -- the message they received from

5 the sales rep 100 percent of the time.

6   Correct, sir?

7 A.   I don't have the word "because."

8 Q.   As a result.

9 A.   Not -- also no. I just say my presentation today was the

10 strong relationship between being a speaker and getting paid

11 and prescribing off-label. That's it.

12 Q.   You're not willing to say, sir, that there is a causal

13 relationship between being a speaker and writing more

14 prescriptions.

15   Correct?

16 A.   Not necessarily. If you want, I'll explain to you why.

17 If you don't, I will not.

18 Q.   You're not willing to go as far as to say it's a causal

19 relationship.

20   True?

21 A.   That's not true. I am more than willing to explain if

22 you are interested.

23 Q.   I'm going ask you some questions about that analysis,

24 sir.

25   But you have assumed that each doctor, for purposes of

1 your damages model, was influenced by the message they

2 received from a sales representative.

3   Correct?

4 A. Correct.

5 Q. All right.

6   But, in fact, your own data shows nearly 2,000 doctors

7 who received visits from Janssen's sales representatives and

8 who did not prescribe any medicine off-label.

9   Right, sir?

10 A. Might well be the case. I don't remember the number.

11 Q. All right.

12   Let's take a look, if I can refresh you, it's tab 44,

13 just for demonstrative, D-9103.

14   MS. BROWN: Mr. Marketos, do you have any objection?

15   MR. MARKETOS: Oh.

16   MS. BROWN: It's tab 44. It's a tab from his report,

17 Exhibit 26 to his report.

18   MR. MARKETOS: No objection. Thank you.

19   MS. BROWN: Sure.

20   THE COURT: You're just showing it as a

21 demonstrative?

22   MS. BROWN: Yes, please.

23   THE COURT: Okay.

24 BY MS. BROWN:

25 Q. All right, sir.

United States District Court
District of New Jersey

1   One of the -- Exhibit 23 to your report, it's a little

2   hard to see, but we'll see if we can get in here. This is a

3   chart from your report that lists prescribers as influenced.

4   Right? According to your definition.

5   Right, sir?

6   A.   Can you tell me what exhibit is it? I have no idea what

7   this page is from.

8   Q.   Yes, sir.

9   A.   I can't remember.

10 Q.   Sure.

11   Exhibit 26 to your report.

12 A.   Okay. Can I look at the exhibit, please, not just the

13 segment of five lines?

14 Q.   Why don't I hand it up to you, sir, and then I'll see if

15 I can get another copy.

16   Okay?

17   MS. BROWN: May I approach?

18   THE COURT: You may.

19   THE WITNESS: Sorry for asking for it. I absolutely

20 don't like to read the five lines and say something about

21 that.

22 BY MS. BROWN:

23 Q.   Professor, we're looking at Exhibit 26 to your report.

24 And one of the things you know is that --

25 A.   Can I look for a second?

United States District Court
District of New Jersey

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 1  Q.   Yes.  Of course, sir.

 2  A.   Yeah.  I appreciate it.  Okay.

 3       Sorry.  Go ahead.

 4  Q.   No problem.

 5       Does this refresh you on one of analyses in your

 6  report, sir?

 7  A.   Yeah.  It's in the report, correct.

 8  Q.   Okay.

 9       And one of the things that we have on this page, one of

10  the pieces of information that we get here, are a listing of

11  physicians that you have identified as influenced.

12       Correct?

13  A.   Yes.

14  Q.   All right.

15       So that means they either received a sales call,

16  attended a speaking event or were a speaker themselves.

17       Correct, sir?

18  A.   That's correct.

19  Q.   All right.

20       And we know that these folks prescribed Prezista and

21  Intelence because we can see that in this column right here.

22       Right?

23  A.   Yes.

24  Q.   And, in fact, some of these folks prescribed a

25  significant amount, almost 1,000 claims of Prezista and
```

United States District Court
District of New Jersey

1 Intelence, for this first influenced physician, Amber

2 McElfresh.

3   Right?

4 A.   Okay.

5 Q.   Yep.

6   But this list of physicians that totals nearly 2,000

7 influenced physicians, they wrote zero prescriptions in the

8 off-label categories that you identified.

9   Right, sir?

10 A.   Okay.

11 Q.   So even though you have assumed that every time a sales

12 rep met with a doctor that doctor was influenced by the

13 off-label message, your data shows almost 2,000 doctors who

14 allegedly received these off-label messages and didn't

15 prescribe at all off-label.

16   Right, sir?

17 A.   I agree.

18 Q.   And we spoke about -- and I think you referenced it a

19 little bit earlier -- there are a number of different factors

20 that go into a physician's decision to prescribe medicine.

21   Correct?

22 A.   That's correct.

23 Q.   And when Dr. Glatt was here, he talked about that.

24   You remember that.

25   Right, sir?

1 A.   I remember very well.

2 Q.   He spoke about the fact that particularly for HIV,

3 prescribing medicine is not a one-size-fits-all proposition.

4   Do you remember that testimony?

5 A.   I remember his testimony.

6 Q.   He spoke about how doctors have to make individual

7 decisions about how to treat their individual patients.

8   Correct, sir?

9 A.   As I said, I don't disagree with all of that. I

10 absolutely agree.

11 Q.   And he identified, as have many witnesses who have

12 testified, all of the different individualized factors that

13 doctors consider when -- when deciding whether to prescribe

14 off-label or prescribe a different medicine or not.

15   Right, sir?

16 A.   But, of course, there are some factors. But if you have

17 100,000 patients and there's such a big difference between two

18 groups, the factors are probably a washout.

19 Q.   Why don't we talk a little bit, then, sir, about those

20 two different groups.

21   Okay, sir?

22   The basis of your opinion here is based in part on your

23 analysis that there is a difference in the amount of

24 prescriptions that are written by influenced physicians and

25 non-influenced prescriptions.

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 1        Correct, sir?
 2  A.    I don't talk about the amount; I talk about the rate.
 3  Q.    Yes, sir.
 4  A.    I want to focus on the rate.  The amount is size biased.
 5  Q.    Yes.
 6        Your opinion is that there is a difference in the rate
 7  of prescribing by influenced physicians and non-influenced
 8  physicians.
 9        Right, sir?
10  A.    Rate of prescribing off-label.
11  Q.    Yep.
12        And one of the things that you know is that there is
13  also a difference between those two groups of doctors.
14        Correct?
15  A.    No.  I checked it.  That was one of the argument of your
16  expert who said that they are infectious disease experts, and
17  I did a report -- analysis that I didn't show in court today
18  that if I take only, only, the doctors on both sides that are
19  infectious disease, the same results are obtained.
20        So the story of my doctors are smarter and more
21  educated and read more papers doesn't work too well in
22  real-life data.
23  Q.    But that's actually not true, Professor Shaked.
24  A.    You can argue with my analysis.  Take a look at my
25  supplemental report.
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United States District Court
District of New Jersey

1 Q. Because what you said to our jury this morning is that

2 you showed an analysis that showed a difference between

3 prescriber -- between influenced prescribers and

4 non-influenced prescribers of almost 11 percent.

5   Right, sir?

6 A. I don't know what the 11 percent cover. It's one of the

7 categories, 11 percent.

8   My point was a minute ago that the doctors --

9 Q. Sir, that was the only question.

10 A. Sorry. Go ahead. Sorry.

11 Q. When you showed that this morning, you showed one

12 analysis.

13   Right, sir?

14 A. One -- I show many analyses. Which one are you talking

15 about?

16 Q. Okay.

17   You showed your original analysis that showed a

18 difference in the rate of prescribing between influenced

19 prescribers and non-influenced prescribers.

20   Can we agree on that?

21 A. That's correct.

22 Q. And that is not the only analysis you've done comparing

23 influenced and non-influenced prescribers.

24   Correct, sir?

25 A. Correct.

1 Q. In fact, you know that our expert critiqued your analysis

2 of influenced and non-influenced prescribers.

3 Correct?

4 A. Correct. And I performed several analyses that

5 contradicted him.

6 Q. And what he did -- and you looked at it, and you reviewed

7 it -- is he produced a report that highlighted the differences

8 between influenced prescribers and non-influenced prescribers.

9 Correct?

10 A. I disagree with that -- with this analysis. Absolutely.

11 Q. I understand you disagree, sir.

12 My question is just you're aware of his analysis and

13 you reviewed it.

14 Correct, sir?

15 A. Yes. Sure.

16 Q. And one of the things Dr. Jena pointed out that you

17 considered in your supplemental report is that the number of

18 influenced physicians who are infectious disease specialists

19 is substantially higher than the number of non-influenced

20 physicians who are infectious disease specialists.

21 Correct, sir?

22 A. That's correct. And I analyzed it.

23 Q. Yes, you did.

24 And when you analyzed it, sir -- and he also pointed

25 out other differences between those two groups of doctors.

United States District Court
District of New Jersey

1   Correct?

2   A.   Yes.

3   Q.   For example, he pointed out the difference between how

4   many antiretrovirals generally those groups of physicians were

5   prescribing.

6   Correct?

7   A.   Correct. I analyzed also that one.

8   Q.   And you know that there are a number of different

9   characteristics between those two groups of physicians that

10   not the same.

11   Correct?

12   A.   Correct. Didn't make any difference for my analysis.

13   Q.   And so what you did, actually, is you went back and you

14   did your analysis again, trying to control for the fact that

15   doctors who have contact with Janssen are known to be a higher

16   rate of specialists.

17   Right, sir?

18   A.   I did go back in response to your expert's reports,

19   that's correct.

20   Q.   Right.

21   And when you went back and you redid your calculations,

22   you tried to account for the fact that there were differences

23   between the two groups of doctors.

24   Is that fair?

25   A.   I -- it's not fair to say that. Let me restate what you

United States District Court
District of New Jersey

1   should say.

2   You should say that I checked, and the two difference

3   that your experts say, one, infectious disease, two, the size

4   of the practice, doesn't make any difference even if I account

5   for it.

6   Q.   Okay. That wasn't my question, sir.

7   A.   Sorry.

8   Q.   My question was, after looking at Dr. Jena's report, you

9   went back to the analysis that you showed our jury this

10   morning and you tried to do it again, accounting for the

11   difference between these doctors that Dr. Jena brought to your

12   attention.

13   Correct, sir?

14   A.   Yeah. I did take his claim and I said, let me see

15   whether it's correct or not. And that conclusion was it's

16   incorrect.

17   Q.   My question was you went back and did the calculation

18   again.

19   Correct?

20   A.   It's not the calculation again. I did it based on what

21   he said, in response to his statement.

22   You sound like I found a mistake and I did it -- you

23   can say whatever you want. I did read his report. I found

24   two items that are interesting. I analyze them, and my

25   conclusion was to say, even I said it today, there is no

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 1 | difference.
 2 | Q.   And, in fact, when you went back and did that analysis,
 3 | the difference in the rate of prescriptions between these two
 4 | groups was substantially smaller than the analysis that you
 5 | showed our jury this morning.
 6 |      Correct, sir?
 7 | A.   I think the median was very different, as far as I know.
 8 | Q.   The mean analysis --
 9 | A.   The median, I say.
10 | Q.   Yep.
11 |      The mean that you showed our jury this morning was very
12 | different than the analysis you did after considering that
13 | these were two different groups of doctors.
14 |      Correct, sir?
15 | A.   The mean was different, but still, there was a
16 | statistically significant difference between the two groups.
17 | Q.   What happened when you tried to account for the fact that
18 | the group of doctors we have contact with are the specialists
19 | in the field?  When you try to account for that, the
20 | difference in the rate of prescribing between the two groups
21 | decreased from the analysis you showed our jury this morning.
22 |      Right, sir?
23 | A.   Hopefully I have a chance to present it in court.
24 |        MS. BROWN:  Your Honor, I'm about to move to a new
25 | topic.  I don't know if this is a good spot to --
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1   THE COURT: Lunch break?

2   MS. BROWN: Yep.

3   THE COURT: All right. Folks, we're going to break

4   for lunch, but it's going to have to be a little longer.

5   We're going to break for 45 minutes. Just to be clear, it's

6   not a security issue, but we had a suspicious package that was

7   delivered. You're able to enter and exit the courthouse, but

8   nobody can be near the loading dock area.

9   So for counsel who may be having lunches brought in,

10   you're going to have figure out some arrangement for them to

11   come to the front of the courthouse or however you guys do

12   that. But because of that delay, I want to give the extra

13   15 minutes.

14   If anything changes in that direction from the Marshal

15   Service, I will let you know. And if there is any issue of

16   security, then we will evacuate and not begin this trial until

17   I have it cleared from the Marshal Service. But for now --

18   and this is not uncommon, but it's a strong reminder to

19   everybody of where we are; that this is not uncommon in a

20   federal courthouse where the Marshal Service has to assess

21   what suspicious packages come in, when we can have a potential

22   bomb threat, when a K9 has to be directed.

23   So I'm just -- it's a good reminder for everybody who's

24   here that this is the world we're living in when you're in the

25   federal courthouse.

 1   So with that, we're going to break for 45 minutes. You

 2   should be able to enter and exit the courthouse.

 3   THE DEPUTY COURT CLERK: All rise.

 4   (Luncheon recess was taken from 12:30 to 1:17 p.m.)

 5   THE DEPUTY COURT CLERK: Please remain seated.

 6   (Brief pause.)

 7   THE DEPUTY COURT CLERK: All rise.

 8   (Jury enters the courtroom.)

 9   THE COURT: All right, folks. Everybody have a seat.

10   Welcome back from the exciting lunch break. But just

11   to be clear, there is no continued threat assessment being

12   made at the courthouse. Everything is okay, and I've spoken

13   to the jurors off-line and the lawyers as well.

14   But with that, why don't we continue proceeding with

15   the examination.

16   And, Professor Shaked, just to remind you, you're still

17   under oath from earlier before lunch.

18   And, Ms. Brown, when you're ready to proceed, you may.

19   MS. BROWN: Thank you.

20   Welcome back, everyone.

21   BY MS. BROWN:

22   Q.   Welcome back, Professor Shaked.

23   A.   Thank you.

24   Q.   A few more topics for you, sir, and we'll conclude.

25   I want to talk to you a little bit some more about some

United States District Court
District of New Jersey

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 1   of the assumptions that you made for your model.

 2        Okay, sir?

 3   A.   Sure.

 4   Q.   One of the things that you have assumed is that, once a

 5   physician receives a visit from a Janssen sales rep, every

 6   subsequent off-label prescription is in your damages model.

 7        Correct, sir?

 8   A.   That's correct.

 9   Q.   So just one visit, no matter how far away in time the

10   subsequent off-label prescription happens, you have put that

11   into the numbers you showed our jury.

12        Correct, sir?

13   A.   It's very rare, but you're correct.

14   Q.   Okay.

15        Well, we are going to look at some examples because it

16   actually happens a lot in the data that you looked at.

17        Right, sir?

18   A.   No.  It's only 6.3 percent of one visit.

19   Q.   And one of the things I wanted to ask you, sir, about

20   this idea that once you receive a visit from Janssen, until

21   the end of time, every time you write an off-label

22   prescription, you put that in the model that you claim the

23   government wouldn't want to pay for it.

24        How come you stop that on December 31st of 2014?

25   A.   How come?
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  1 Q.   Yes.

  2 A.   Naturally, to me, should not be stopped, but I was

  3 advised to calculate only to the end of 2014.

  4 Q.   So your methodology actually assumes that once a doctor

  5 receives a visit from a Janssen sales rep, every prescription

  6 until the end of time is tainted.

  7   Right?

  8 A.   Correct. Tainted is a good word.

  9 Q.   All right.

 10   But for a reason you and I don't understand, the

 11 lawyers told you to stop it on December 31st, 2014.

 12 A.   I never ask why this was provided to me, the date.

 13 Q.   Okay.

 14   Well, did you say, like, alert, alert, I think the

 15 government is owed money beyond this? Did you raise that

 16 concern?

 17 A.   No. I -- this not the kind of thing that I should

 18 challenge the lawyers. This is more legal.

 19 Q.   I guess the answer really is you're not making a

 20 determination if the government really is owed this money or

 21 not. So that's one of the reasons you didn't tell them, Why

 22 are we stopping in 2014?

 23 A.   No. The reason I didn't tell them is because it's not my

 24 function to tell them the parameters of this litigation.

 25 Q.   Were you curious as to why they told you to stop your

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 1  calculations on December 31st, 2014?
 2  A.   Not really.  I can understand that they might have their
 3  own reason.
 4  Q.   All right.
 5       Let's take a look, sir.  I want to talk to you about
 6  this idea that a single visit from a sales representative
 7  taints all off-label prescriptions for the end of time.  And
 8  we looked at some of the data in your report, and you produced
 9  a lot of supplemental tables to us.
10       Right, sir?
11  A.   Yes.
12  Q.   All right.
13       And one of the things you know, Professor Shaked, that
14  was available to you but that you did not look at is something
15  called "call notes."
16       Right, sir?
17  A.   "Call notes."
18  Q.   Yes, sir.
19       Do you know what that is?
20  A.   Yeah, yeah.
21  Q.   Okay.
22  A.   This is a database with calls.
23  Q.   Right.
24  A.   I did take a look at it very early, but I just use the
25  dates and so on, not the contents.
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United States District Court
District of New Jersey

1 Q.   Not the contents.

2 A.   No.

3 Q.   So one of the things our jury has heard about is when

4 sales reps go to visit a physician, they log what took place

5 at that visit in something called a "call note."

6   And you're familiar with that.

7   Right, sir?

8 A.   That's correct.

9 Q.   And one of the ways if you wanted to know what message

10 was delivered at a sales meeting, one of the things you could

11 do is take a look at the call notes.

12   Correct, sir?

13 A.   I can, but I was also reading -- it's correct.

14   However, if you want to say however, I was told that

15 people were requested not to leave anything in writing,

16 especially about off-label.

17 Q.   And you were told that by the lawyers bringing the

18 lawsuit?

19 A.   No. I read -- I told you. I read about seven or eight

20 depositions, and more than one person said, We were advised

21 not to give anything in print.

22 Q.   Did you look at the call notes themselves to see for

23 yourself if that testimony was credible and accurate?

24 A.   I don't recollect. I looked at the call notes way back

25 and did not use the content for my analysis.

United States District Court
District of New Jersey

1 Q.   All right.

2   One of the doctors who has no call notes but a single

3 entry for a sales visit is Dr. Ellen Yang. She was -- we'll

4 give it one second here -- called by a Janssen sales

5 representative once in the middle of 2006.

6   All right. We have no call notes or information about

7 what took place on that call.

8   In 2011, so five years later, she wrote a couple of

9 prescriptions that were considered on label. And then in

10 2014, she wrote a couple of prescriptions that were considered

11 off label, according to your model.

12   And your methodology, sir, is that a single meeting in

13 the middle of 2006, for which we have no entry as to what was

14 discussed, influenced Dr. Yang now almost ten years later to

15 write certain off-label prescriptions for Prezista.

16   Correct, sir?

17 A.   That's correct.

18 Q.   Okay.

19   And so the basis, then, for that theory, sir, is that:

20   Number one, Dr. Yang remembered a solitary visit from a

21 Janssen sales representative nearly a decade earlier.

22   Correct, sir?

23 A.   No, that's -- that's not the point here.

24 Q.   Well, for it to have influenced Dr. Yang ten years later,

25 she would have had to at least recall that ten years earlier,

 1 somebody from Janssen came to visit her.

 2   Right, sir?

 3 A.   I don't know. I didn't interview her. I don't know.

 4 Q.   Right.

 5   You didn't talk to Dr. Yang to say, Dr. Yang, do you

 6 remember anything that took place in the year 2006?

 7 A.   I was not concerned about your case of one call. And I

 8 will tell you -- tell you why if you want.

 9 Q.   Sir, did you say you were not concerned?

10 A.   No, not at all.

11 Q.   Okay.

12   Let's take a look at another example from your data,

13 sir. This is an example of another doctor, Dr. Hoskinson, who

14 similarly received one visit from a Janssen sales

15 representative in the middle of 2009.

16   Do you see that, sir?

17 A.   Yeah. I see it.

18 Q.   And then he sort of has a mixture. The blue is the,

19 quote, on-label and the red is the off-label. He has a

20 mixture of those prescriptions from 2010 to 2014.

21   Correct, sir?

22 A.   That's correct.

23 Q.   And your damages model assumes that a single visit from a

24 Janssen sales representative in the middle of 2009 meant that

25 all of those red prescriptions should not have been paid or

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 1   reimbursed by the government.

 2         Correct, sir?

 3   A.   That's correct.

 4   Q.   And similarly, like Dr. Yang, you didn't speak to

 5   Dr. Hoskinson to determine whether he even had a recollection

 6   of anybody visiting with him.

 7         Correct, sir?

 8   A.   I -- I'm not sure.  What are you -- sorry.

 9         Can you repeat, please?

10   Q.   Just like when we discussed Dr. Yang in the prior

11   example, you didn't speak to the doctor in --

12   A.   No, I didn't speak.

13   Q.   -- this example to find out if it's correct, as you have

14   assumed, that a single visit from 2009 hijacked his medical

15   judgment in 2011, '12, '13, and '14.

16         Right, sir?

17   A.   Once again, I was not concerned, and I am more than

18   willing to tell you why.

19   Q.   All right.

20         And let's take a look at Dr. Barbara Beard.  This is

21   also a single visit with no calls in 2007, and then

22   prescriptions beginning almost two years later that you have

23   concluded the government would not have wanted to reimburse.

24         Correct, sir?

25   A.   That's correct.
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1   Q.   One of the things about these examples, sir, the last

2   three examples we looked at, they all involve a single visit

3   from a sales rep.

4   Correct, sir?

5   A.   That's correct.

6   Q.   And you know, because it's on your reliance list, that

7   Mark Wilhelm testified about how many sales visits he believes

8   is needed before a doctor appreciates or remembers a sales

9   message.

10   Right, sir?

11 A.   I don't remember.

12 Q.   Do you remember Mr. Wilhelm testifying that he believes

13 it is eight visits from a sales rep before a doctor remembers

14 a message?

15 A.   I don't remember it. I take your word as correct. I

16 have no recollection.

17 Q.   One of the things you could have done in analyzing this

18 data but did not do is sort the data by how many visits

19 doctors received from sales representatives.

20   Correct, sir?

21 A.   I did sort it. I did took -- did take a look at that,

22 and only 324 out of 5,177 got the one call. So you got the

23 three of them and you show to the jury; that's fine.

24 Q.   So it's actually almost 800 physicians who have five or

25 less visits. Does that comport with your look at the data,

1   sir?

2   A.   I know that only 6.3 percent of the 5,177 physicians,

3   what you show now to the jury. If you take it out of context,

4   you know, out of proportion, that's fine.

5   Q.   This is the context, though, sir, because these

6   prescribers are in your model.

7   Right, sir?

8   A.   My model, correct.

9   Q.   And you never spoke to any of them.

10   Correct?

11   A.   That's correct.

12   Q.   And you operated with the assumption that a single sales

13   visit from a Janssen sales representative influenced

14   prescribing physicians years later.

15   Correct, sir?

16   A.   Not this early. It might be that somebody from the

17   clinics bought off label -- prescribe off label. I don't say

18   that this person for ten years was not involved in influencing

19   other people. Or some cases that I worked on -- and I

20   realized that the person stopped prescribing, but people from

21   her clinics did prescribe.

22   So the fact that there is a gap doesn't mean that the

23   person was not involved in more off-label.

24   Q.   But you don't have that information, sir. The

25   information that you have is a single visit from a sales

1 representative followed by what you deemed off-label

2 prescriptions years later.

3   That's the data you have.

4 A.   Right. You have only one chance to make a first

5 impression.

6 Q.   I'm not sure what that means, sir, but we're going to

7 move on to another topic.

8   Okay?

9 A.   If you want. It means that the first meet is really

10 important.

11 Q.   Okay.

12   Let's talk a little bit about how you treat

13 prescriptions that were written by a second prescriber.

14   Okay, sir?

15 A.   Okay.

16 Q.   What you have done as part of your damages model is that

17 you have assumed if a prescription begins with someone you

18 consider to be influenced --

19   You with me?

20 A.   Yes.

21 Q.   And then that patient switches doctors and goes to a

22 non-influenced doctor, you count in your model all of the

23 prescriptions that were written by that second doctor.

24   Accurate, sir?

25 A.   That's correct.

United States District Court
District of New Jersey

1   Q.   And what that really means is that the taint, the Janssen

2   sales rep taint, traveled with a patient.

3   Right?

4   A.   No, it doesn't mean that. It means that your expert --

5   if you look at his first report, paragraph 40, you say, "It's

6   very unlikely that people change regimen." Your own expert,

7   Section 40 of his report, you will see that written there.

8   And Dr. Glatt also said that.

9   Q.   And Dr. Glatt was here, right, sir, and he talked about

10   this very issue, and you remember that.

11   Right, sir?

12   A.   He said that very rarely you change regimen. It's

13   possible, but very rarely.

14   Q.   What Dr. Glatt told our jury is that it is critical to

15   reassess every patient you see, every time you see them.

16   Right, sir? You remember that?

17   A.   No, I remember that he said that you very rarely change

18   regimens. That's what I remember.

19   Q.   Dr. Glatt said that if an HIV patient switches doctors,

20   the new doctor exercises his or her own judgment in deciding

21   what medicine to prescribe.

22   You remember that testimony from Dr. Glatt?

23   A.   Right. From your expert and other sources in this case,

24   it doesn't happen too frequently.

25   Q.   I appreciate your testimony, sir, but that wasn't my

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 1  question.

 2       My question was do you recall when you were sitting in

 3  the courtroom that Dr. Glatt testified that if an HIV patient

 4  switches doctors, he believes the new doctor exercises his or

 5  her own judgment in deciding what medicine to prescribe.

 6       Do you recall that testimony?

 7  A.   Sure.

 8  Q.   All right.

 9       Let's take a look, sir, if we could --

10       MS. BROWN:  Mr. Morales, would you show us the

11  demonstrative, 52, please.

12  BY MS. BROWN:

13  Q.   Let's start right here, sir, just with an example of how

14  your methodology works.

15       This is a prescription that you consider to be off

16  label that was initiated by a doctor, an influenced physician,

17  in 2011.

18       Do you see that?

19  A.   Yes.

20  Q.   And this doctor wrote one off-label prescription for

21  purposes of our analysis here.

22       Do you see that?

23  A.   Yes.

24  Q.   And this is actually -- if you look down at the bottom,

25  sir, there's a patient ID.  This comes from your report.  This
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United States District Court
District of New Jersey

 1 is real data in your actual report.

 2 A.   Okay.

 3 Q.   Okay?

 4   And then if we go to the next one, what happened was

 5 this patient changes doctors and a new doctor, who was not

 6 influenced, according to you, by Janssen, continued to write

 7 59 of these off-label prescriptions.

 8   Do you see that, sir?

 9 A.   Yes.

10 Q.   That doctor who wrote 59 of the 60 prescriptions we're

11 looking at here had no contact with Janssen.

12   Correct, sir?

13 A.   That's correct.

14 Q.   But what happens, if we go to the next clip, is that for

15 purposes of your math that you showed the jury this morning,

16 you count all 60 prescriptions as if they had been written by

17 the, quote, influenced physician.

18   Correct?

19 A.   That's correct. That's based on reasonable assumptions.

20 Q.   So 59 of these prescriptions that were written by a

21 doctor who we never saw, talked to, paid, looked at, 59 of the

22 60 get attributed to the person who wrote one prescription.

23   Correct?

24 A.   Yeah. You are correct, but there is a reason for that.

25 Q.   A little more, sir, on the lifelong prescription.

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 1        As it relates to doctors who were speakers, you don't

 2   just consider the future off-label prescriptions in your

 3   damages model; you also consider future on-label

 4   prescriptions.

 5        Correct, sir?

 6   A.   For speakers, yes.  For the anti-kickback you talked

 7   about.

 8   Q.   Yes, sir.

 9   A.   Yes.

10   Q.   All right.

11        So if you identify a speaker like Dr. Ricky Hsu, who

12   our jury heard from virtually last week, if you identify a

13   doctor like Dr. Hsu, you identify the first date that he spoke

14   for us, and every Prezista and Intelence prescription he every

15   wrote after that date you have in your model.

16        Right, sir?

17   A.   That's correct.

18   Q.   And you know Ricky Hsu -- your theory is that all of

19   those prescriptions after this individual spoke for us were

20   tainted by the money we gave him to speak.

21        Correct?

22   A.   I did not make this assumption.  I was advised, the

23   anti-kickback, I have to start from the first time he spoke

24   all the way to the end.  You say I assume.  I did not assume

25   anything.
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United States District Court
District of New Jersey

1   Q.   And you know that Dr. Hsu, when he was here, he was asked

2   questions by Relators' counsel about this idea that somehow

3   his medical judgment was influenced by the money he received

4   from us for speaking on the bureau.

5   Do you recall that?

6   A.   Yes.

7   Q.   And you recall Dr. Hsu testified he was extraordinarily

8   offended --

9   MS. BROWN: Could I have the ELMO, Mr. Morales.

10   BY MS. BROWN:

11   Q.   That he was actually extraordinarily offended by that

12   suggestion.

13   Were you here for that testimony, sir?

14   A.   Yes, I was.   It was a little bit of emotion, yeah.

15   Q.   Yeah.

16   "I find your allegations to be extraordinarily

17   offensive because you have no idea and no practicing concept

18   of our wanting as HIV providers the needs to take care of our

19   patients as best as possible."

20   Do you see this testimony, sir?

21   A.   Yes.

22   Q.   He said, "We're in it not because we're being paid by a

23   company.   We choose the right drug for the right person

24   because it's best for them."

25   You see that, sir?

United States District Court
District of New Jersey

1 A.   Yes.

2 Q.   And he pushed back against the very assumption of your

3 model. "You're trying to correlate me being paid, which

4 includes reimbursement, research, expanded access, everything

5 else. You're trying to insinuate brand-new indication. It's

6 offensive. It's ridiculous. And you should know that

7 yourself."

8   That's what Dr. Hsu had to say when he was questioned

9 about the assumption that you made for the lifelong taint of

10 Ricky Hsu's prescriptions.

11   Right sir?

12 A.   You asked me whether he said it. Yeah, he did say it.

13 Q.   Let's take a look, sir, at another example of some real

14 data from your report.

15   This is Dr. Kubota, who is identified as a speaker who

16 actually only spoke one time for us in late 2006.

17   Do you see that, sir?

18 A.   Yes.

19 Q.   And he was paid approximately, I think, $2,500 for that

20 speaking event. And your model, your damages model that you

21 presented to our jurors, assumes that speaking once in 2006

22 meant that every additional prescription that is shown on this

23 graph is in your damages model.

24   Right, sir?

25 A.   Yeah. If he delivered the speech, that's correct.

United States District Court
District of New Jersey

1   Q.   And it doesn't matter to you if he delivered a speech on

2   Intelence or Prezista.

3   Right, sir?

4   A.   Correct.

5   Q.   If he has delivered -- we're looking at Prezista claims,

6   and he also has -- I'll pull it up here -- claims for

7   Intelence that are included in your model.

8   Right, sir?

9   A.   Yes.

10 Q.   And you don't know, and truthfully it doesn't matter to

11 your opinion, whether he spoke about Prezista or Intelence.

12   Right, sir?

13 A.   Not at all.

14 Q.   As long as he spoke about one of those two medicines,

15 every medicine of either type, Prezista or Intelence, on

16 label, off label, for the rest of time you considered to be in

17 your damages model.

18   Right, sir?

19 A.   Absolutely.

20 Q.   Okay.

21   So this one speaking event for $2,500 in 2006 meant

22 that Dr. Kubota could not prescribe a medicine, Prezista or

23 Intelence, for a patient that is receiving insurance from the

24 government.

25   Correct?

United States District Court
District of New Jersey

1   A.   I don't say -- you said never prescribe? He could

2   prescribe as much as he wants.

3   Q.   Well, but you know -- for example, Medicare Part D, it

4   helps patients pay for these medicines.

5   Right?

6   A.   That's correct.

7   Q.   Right.

8   And so under your model, he should never have

9   prescribed Prezista or Intelence to somebody who was trying to

10   get insurance help from the government.

11   Right?

12   A.   I don't know. But if he's influenced and he write this

13   prescription, based on my model this amounts are -- actually

14   should be part of the damages. That's it.

15   Q.   And whether or not CMS agrees with that, sir, whether or

16   not CMS agrees that once you speak once for Janssen they don't

17   want to pay for any prescription you ever write for those

18   medicines again, you don't know the answer to that.

19   Right?

20   A.   I don't know. But I work for the Department of Justice,

21   and they're very, very nervous about speaking program. I can

22   tell that you.

23   Q.   You used to work at the Department of Justice?

24   A.   I said I worked with them.

25   Q.   Worked with them?

United States District Court
District of New Jersey

1   A.   Correct. On cases of false claim and so on. And they're

2   very, very nervous about these program.

3   Q.   That's interesting.

4   So in the past you have testified as an expert for the

5   Department of Justice in cases like this?

6   A.   Not about off-label, but about cases of False Claims Act.

7   And I know that speaker programs have really bad reputation

8   nationwide. I can tell you it's in the public domain.

9   Q.   And this is a False Claims Act case, though, sir, where

10   you are not testifying for the Department of Justice.

11   Right?

12   A.   Which one, this one?

13   Q.   Right here.

14   A.   No.

15   Q.   Right.

16   You're not here for the Department of Justice. You're

17   here for the lawyers bringing the lawsuit.

18   Right?

19   A.   I am here on behalf of myself testifying, not for them.

20   On behalf of lawyer retained me.

21   Q.   That's another good point that you raise, sir.

22   You're being compensated by these lawyers.

23   Right?

24   A.   Absolutely.

25   Q.   You have retained your own independent professional

 1   judgment that you believe you're exercising in this case.

 2   Right?

 3   A.   Yes. I do it for 50 years. And if every time I would

 4   change my mind -- my opinion based on who pays me, I wouldn't

 5   be around here.

 6   Q.   Absolutely, sir.

 7   The fact that you are being compensated for your

 8   professional time, you do not believe that hijacks your

 9   professional judgment in serving as an expert witness here.

10   Right?

11   A.   As an expert witness, I am always objective.

12   Q.   You spoke a bit, sir, about ADAP and Medicaid.

13   Do you recall that, sir?

14   A.   Yes.

15   Q.   All right.

16   And you put up this slide here during your

17   presentation. Reimbursements by government payors Medicare,

18   Medicaid, and ADAP.

19   Do you see that, sir?

20   A.   Yes.

21   Q.   And you purport, based on this data, to have information

22   about whether the off-label was initiated by an influenced

23   physician or by a non-influenced physician.

24   Do you see that?

25   A.   Yes.

1   Q.   And that -- so something's wrong with this chart. Do you

2   know what it is?

3   A.   Why won't you tell me. I'm sure you will tell me.

4   Q.   Sure.

5   You don't have that information from ADAP. You know

6   that.

7   A.   Yes. But I have -- I'm in statistics for many, many

8   years. I know how to do estimates if they're reasonably

9   acceptable. So the fact that I didn't have a relationship

10   within the -- with the patient and the doctor in ADAP, I have

11   a very good way, since I described to my report, how to

12   estimate it.

13   Q.   Okay. That wasn't my question.

14   When it comes to the data you got from ADAP, you do not

15   have data on whether the prescriptions were written by

16   influenced physicians or non-influenced physicians.

17   Correct?

18   A.   Absolutely. And I write it in my report more than once.

19   Q.   Right.

20   A.   Denied it. I just estimate it in a very legitimate,

21   acceptable way.

22   Q.   Right.

23   The ADAP data you received is a lump-sum number.

24   Correct?

25   A.   I have a sum of the different -- sorry -- different drugs

1   by quarter and year and so on. By quarter, right. And so I

2   don't have just a link between the ADAP -- health care

3   professional and the patient.

4   Q.   Right.

5   You can't tell from that ADAP data the identity of the

6   physician who prescribed a Prezista or Intelence medicine.

7   Correct, sir?

8   A.   Correct.

9   Q.   All right.

10   You can't link, for example, particular physicians who

11 had prescriptions reimbursed under ADAP to physicians who had

12 any contact with us.

13   Correct?

14 A.   Correct. That, I was not there, but I have a very

15 conservative way to estimate it.

16 Q.   The other thing, sir, I want to ask you about is state

17 funding.

18   Do you have any idea --

19 A.   Which one? I'm sorry.

20 Q.   State. I want to talk about states at issue --

21 A.   Oh, state funding.

22 Q.   State. Yep.

23   Do you have any idea, sir, why this lawsuit includes 26

24 states?

25 A.   No. That's -- by now you know I don't deal with any of

 1   the legal aspects of this case, no.

 2   Q.   All right.

 3   Well, in figuring out how much money you thought should

 4   be attributed to these states, did you look at the individual

 5   requirements that each state Medicaid program has for whether

 6   or not these medicines are reimbursable?

 7   A.   No.

 8   Q.   Do you know of anybody in this entire lawsuit for the

 9   Relators who has done that?

10   A.   I -- you cannot ask -- ask other people, not me.

11   Q.   All right.

12   A.   If I know about other people, I'm not here to opine on

13   it.

14   Q.   You also, sir, are aware that Medicaid requires

15   pharmaceutical companies like ours to provide rebates.

16   Right, sir?

17   A.   Yes.

18   Q.   And that's essentially the pharmaceutical company paying

19   the Medicaid program some money.

20   Right? Paying back some money?

21   A.   Correct.

22   Q.   You did not factor rebates into the damages numbers you

23   put up for our jury.

24   Correct?

25   A.   No, no.

 1 Q.   And the reason you didn't do that is because the lawyers

 2 told you not to.

 3   Right?

 4 A.   Lawyers told me, when I told them to conservative

 5 assumption that they made, they said, Let's leave the rebate

 6 out.

 7 Q.   So you told them you thought you were being conservative,

 8 and they said, Don't worry about the rebates. It all comes

 9 out in the wash.

10 A.   They didn't say "the wash." They just advised me not to

11 account for it.

12 Q.   Okay.

13   But you referenced something about a conservative

14 approach.

15   Did they tell you, Don't worry about the rebates?

16 A.   They never said "don't worry." That's a wording that

17 sounds good in courtroom. But I didn't quote that one. I

18 just said that they say, Don't account for rebates.

19 Q.   Did you raise with the lawyers that you knew that some of

20 the money in your damages model had not been paid by the

21 government because Janssen gave them rebates?

22   MR. MARKETOS: I'm sorry. Objection, Your Honor.

23 That assumes facts not in evidence.

24   THE COURT: Let me see you folks for a moment.

25   (Sidebar begins at 1:47 p.m.)

1   THE COURT: Sorry. You're asking him what?

2   MS. BROWN: He knew about some of the damages money

3   was paid back in rebates, and he was instructed to ignore it.

4   THE COURT: Is there evidence of that?

5   MS. BROWN: Yeah. His testimony, Judge, right here.

6   He --

7   THE COURT: Well, he said he didn't account for

8   rebates. But you're asking him, but you know Janssen paid

9   money back in rebates.

10   MS. BROWN: Yeah.

11   THE COURT: Where is the evidence of that, that

12   Janssen did that?

13   MS. BROWN: He said it. He knew it's 3 to 4 percent,

14   and he was advised not to take it into account.

15   THE COURT: "He said that" meaning this witness said

16   that?

17   MS. BROWN: Yes.

18   THE COURT: Okay.

19   MS. BROWN: Yes.

20   "Did you factor in rebates?

21   "No.

22   "Why not?

23   "I was advised by counsel not to account for that.

24   They said that it's the judge or jury, whatever. We can

25   always account. It's only 3 or 4 percent. The counsel

United States District Court
District of New Jersey

 1   advised me not to take it into account."

 2   THE COURT: Right. He did say that.

 3   MR. MARKETOS: Yeah, because it's an -- this has got

 4   to do with setoff post-verdict. So they're going to be having

 5   -- they're going to have to come forward and put on evidence

 6   on what they believe needs to be set off post-verdict. And

 7   she's asking him about rebates from damages pre-verdict.

 8   And that's the problem. They have put forth no

 9   evidence of what the rebate amount is, and they're trying to

10   get a rebate off the damages that is a -- for Your Honor to

11   take into account post-verdict. She's trying to put it on

12   through this witness as if it's a discount to the damages

13   amount to the government.

14   MS. BROWN: But he testified that he thought it was.

15   He thought there were 4 percent of rebates in here that

16   actually the government didn't pay, and he was instructed not

17   to consider them. I mean, that's fair. He could have put it

18   like all these other deductions. He could have said after

19   it -- minus 4 percent.

20   THE COURT: I'll overrule the objection because he

21   testified to it. So if you want to clarify it on redirect,

22   you can. But I'm going to allow the question because there's

23   testimony that he mentioned 3 or 4 percent rebates. So he --

24   MR. MARKETOS: Yes. They're asking about 3 to

25   4 percent rebates. I just want Your Honor to understand, this

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 1  would be an issue of offset that they would argue post --

 2          THE COURT:  All right.  But I'm going to allow the

 3  question for now.  And if you want to clean it up on

 4  redirect -- but okay.

 5          MR. MARKETOS:  And I can argue the charge to the jury

 6  in closing it, right?  In other words, that this is not to be

 7  taken into account with damages because a rebate is an offset

 8  that they would be arguing --

 9          THE COURT:  I'm not going to decide today what can be

10  argued or not argued, but I'm going to allow that questioning

11  for now.

12          MS. BROWN:  Thank you, Judge.

13          MR. MARKETOS:  Thank you, Your Honor.

14          (Sidebar was concluded at 1:50 p.m.)

15          (Open court.)

16          MS. BROWN:  May I proceed, Your Honor?

17          THE COURT:  You may.

18  BY MS. BROWN:

19  Q.  Professor, we were talking about this idea of

20  pharmaceutical companies paying rebates to the government.

21  A.  Right.

22  Q.  You're familiar with that.

23      Right, sir?

24  A.  Yes.

25  Q.  And you believe that there is a certain percentage of the
```

 1 | damages number you have here that likely are subject to

 2 | rebates.

 3 | Correct?

 4 | A.   Rebates are typically 3 percent.

 5 | Q.   Yep.

 6 | And you were instructed not to consider those rebates

 7 | in your model.

 8 | Correct, sir?

 9 | A.   That's correct.

10 | Q.   All right.

11 | Professor Shaked, you are charging the lawyers who

12 | hired you $825 an hour.

13 | Is that right, sir?

14 | A.   Might well be. I own the company, but I don't do no

15 | billing nor the collection, but it sounds close.

16 | Approximately 800.

17 | Q.   Okay.

18 | A.   And I started this project much less. Five years already

19 | of bulk of this project.

20 | Q.   Okay.

21 | I'm just asking what your hourly rate is.

22 | A.   It's -- 800 is close enough. I don't know exact. Might

23 | be 820, might be 850.

24 | Q.   Okay.

25 | You're not sure how much you're charging to be here

1 today?

2 A.   No.   Finally we agree that.   Really, one person doing the

3 invoicing and one doing the collection, and I am overseeing

4 everything else, but not the detail.   But I think it's about

5 800.   That's correct.

6 Q.   Okay.

7   And for the time that you've been sitting in the trial,

8 watching or reading the trial transcripts, do you intend to

9 bill the lawyers for that time?

10 A.   Yes.

11 Q.   All right.

12   And that will be at your similar approximately

13 $800-an-hour rate.

14   Right, sir?

15 A.   Yeah.   Depends.   Yeah.

16 Q.   Okay.

17   When -- it depends?

18 A.   Yeah.   I don't -- I don't charge for every one hour that

19 I work.   I usually charge only for a portion of the time.

20 Q.   How do you determine what to charge and what not to

21 charge?

22 A.   Like, if I just do reading per se, not working with a

23 client, is -- I charge less hours, not less hourly rate.   Less

24 hours.

25 Q.   I understand.

United States District Court
District of New Jersey

1   In 2020, when we took your deposition, you had

2   estimated that you had worked approximately 200 hours on the

3   case.

4   A.   Yes.

5   Q.   Since 2020, in the last four years, approximately how

6   many hours do you think you've worked on the case?

7   A.   Another 150 or 200.

8   Q.   All right.

9   So does that put the total amount that your firm that

10   you own has made for this engagement close to a million

11   dollars, sir?

12   A.   No. A, it's not a million, and, B, it's me.

13   I have a firm, I have people working for me. This is

14   for the firm, not for me.

15   Q.   Yes, sir.

16   I didn't mean to suggest you're putting the money in

17   your pocket. I meant to suggest the amount of money that your

18   firm is charging these lawyers is close to a million dollars

19   for your work on this case.

20   Correct?

21   A.   I don't have any clue what the total.

22   Q.   When we asked you in 2020, you said you had billed 200

23   hours, and that was approximately $500,000.

24   Do you recall that testimony?

25   A.   For five people combined, not for me.

United States District Court
District of New Jersey

1 Q.   Yes, sir.

2 A.   Oh, yeah. It makes sense.

3 Q.   When you say you've continued to work on the case, your

4 team, some of the folks who are here, they've continued to

5 work on the case, too.

6   Right?

7 A.   Yes. As needed.

8 Q.   Sure.

9   And so if you billed another 200 hours, they billed

10 another couple hundred hours as well.

11   Right, sir?

12 A.   I'm not sure it's much. Most of the hours are mine.

13 Q.   Right.

14   So at the very least, sir, you have billed more than a

15 half a million dollars on this case, which is the number you

16 told us back in 2020.

17   Right, sir?

18 A.   It's for five years, correct.

19 Q.   Yep.

20   And that's interesting that you should say that

21 because, when you look at the amount of money that speakers on

22 the speakers' bureau made, you understand most of that is over

23 a period of about eight years.

24   Right, sir?

25 A.   It depends how many on the speaker program, yeah.

United States District Court
District of New Jersey

1   Q.   Like Dr. Hsu, for example, he started speaking for us in

2   2006.

3   Right, sir?

4   A.   I don't know when he started.

5   Q.   Do you recall him testifying that he was on the bureau

6   for the entire time period at issue in this lawsuit?

7   A.   Yes.

8   Q.   And you would agree when you're looking at the amount of

9   compensation a professional receives, you should consider the

10 time period that they've performed services.

11   Right, sir?

12 A.   I don't do consideration for the doctors. This is own

13 business. He obviously has to charge for his time. That's

14 what I can tell you. The rest of it, I don't know.

15 Q.   I'm talking about you, though. When you charge for your

16 time, you pointed out to me you have to consider, I worked

17 over five years.

18   Right?

19 A.   Correct.

20 Q.   Because it's reasonable, if you're trying to evaluate a

21 professional's time, to consider how long they worked.

22   Right?

23 A.   Depends on the case.

24 Q.   All right.

25   Let's just talk about you. It's reasonable to consider

 1 how much time you worked.

 2   Right, sir?

 3 A. It's -- it's important for what? I am not sure what the

 4 question.

 5 Q. If we want to evaluate how much money you made on this

 6 case --

 7 A. Right.

 8 Q. -- we should consider how long you worked on the case.

 9   Right, sir?

10 A. Correct.

11 Q. And even though your firm has been paid more than half a

12 million dollars working on this matter, you believe that you

13 retained your independent, professional ability to evaluate

14 the evidence.

15   Right, sir?

16 A. That's correct.

17 Q. You don't believe that the lawyers who hired you, who

18 appear listed on your website, you don't believe they hijacked

19 your ability to make an independent judgment about this case.

20   Right, sir?

21 A. They absolutely did not because the number of cases that

22 I turn down is much higher than the cases that I take,

23 including this firm. This firm call me few times, and I said,

24 sorry, I can't do the case.

25   So I cannot -- would never be able to be -- charge that

1 I take every case. I reject about two-thirds of the cases

2 that I get calls for.

3 Q.   Certainly, sir, you've had the opportunity to work with

4 the Berger Montague law firm before this case.

5   Right, sir?

6 A.   Very few times, yes.

7   MS. BROWN: Thanks very much, Professor Shaked. I

8 have no more questions for you. Appreciate it.

9   THE WITNESS: Thank you.

10   THE COURT: Thank you, Ms. Brown.

11   Mr. Marketos, any redirect?

12   MR. MARKETOS: Yes, Your Honor. Thank you.

13   If I can just grab the mic.

14   MS. BROWN: Of course, sorry.

15   THE COURT: Ms. Brown, are you going to be able to

16 take down that display also?

17   MS. BROWN: Of course.

18   MR. MARKETOS: I might use it, Your Honor.

19   MS. BROWN: Do you want me to put it back?

20   MR. MARKETOS: I might use it myself, Your Honor.

21   THE COURT: All right.

22   THE WITNESS: With the photos.

23   MR. MARKETOS: With the photos and the testimony.

24   THE COURT: All right. Fair enough. I thought we

25 were done with it.

United States District Court
District of New Jersey

    1   MR. MARKETOS: Thank you, Your Honor, I appreciate

    2   it.

    3   (REDIRECT EXAMINATION BY MR. MARKETOS:)

    4   Q.   Hello, Professor Shaked.

    5   Did we ever send you to Hawaii?

    6   A.   No. I've been only once in my life.

    7   Q.   Just so you know, we didn't pay you and Berger Montague,

    8   that's our friends back here, you've been working with them

    9   for about five years, the law firm that originally started

   10   helping the Relators.

   11   Right, sir?

   12   A.   Right. You put me in a very cheap hotel.

   13   Q.   Yeah, sorry.

   14   A.   In Brimstone. They're very cheap one.

   15   Q.   And I'm from the law firm of Reese Marketos. And these

   16   are my partners and colleagues and colleagues here. We

   17   started working with you to prepare for trial in this case.

   18   Right?

   19   A.   That's correct.

   20   Q.   Okay.

   21   Just to be clear, you're not prescribing any drugs that

   22   affect a patient's health, are you?

   23   A.   No, not at all.

   24   Q.   All right.

   25   Do you recall anybody ever sending you to steak houses

1   in Hawaii before you decided to give your expert opinion?

2   A.   I wasn't very lucky.

3   Q.   And if, in fact, we had sent you to Hawaii and Little

4   Rock, we paid you $2,500 an hour, time over time over time

5   over time, it's possible that people might think we were

6   starting to affect your objective judgment.

7   Right, sir?

8   A.   It might be the case. Your description is not relevant

9   to my life.

10   Q.   Yeah.

11   Because that doesn't happen in your life.

12   A.   I don't go to expensive places, nor to Hawaii.

13   Q.   Professor, Dr. Hsu was here to testify. And after we

14   reminded him about the amount of money that he's made from

15   pharmaceutical companies, he was reminded of the fact that

16   almost all of the pharmaceutical companies that he got paid by

17   were in trouble for paying kickbacks to doctors.

18   Do you recall that?

19   A.   Yes.

20   Q.   And then, at the end of his testimony, we asked him

21   whether or not he personally believed he wasn't influenced by

22   the payment money, and he said, "I hope that is not the case.

23   I don't think so." That's one doctor that Janssen called.

24   Do you know how often Ricky Hsu was contacted by

25   Janssen's marketing department, sir?

1   A.   Only 1,014.

2   Q.   1,014 times.

3   Do you know that he gave and was paid to speak over 200

4   times on Janssen's Promotional Speaker Bureau?

5   A.   My next life, I want to be Dr. Hsu.

6   Q.   Yeah, I understand.

7   And he believed himself that he wasn't influenced by

8   the payment from Janssen and other pharmaceutical companies.

9   What do you understand is the purpose of the

10   Anti-Kickback Statute?

11   A.   I don't see -- that's a legal question. I prefer not

12   to intend of anti -- you know, with all respect.

13   Q.   All right. It's not for us to do.

14   Right?

15   A.   It's not for me to do.

16   Q.   All right. It's not for you.

17   You're here to calculate the amount of money that came

18   out of prescriptions from those doctors.

19   A.   Absolutely like that. I came with no opinion of what I

20   get, and it's very unbiased. I don't go into legal stuff. I

21   have tough time without it.

22   Q.   We'll come back to Dr. Hsu in a moment, if we could.

23   Could -- I want to dispense with one notion, sir.

24   MR. MARKETOS: Could we pull up our slide

25   presentation, Ms. Johnson. I'd like to turn to Slide 56.

United States District Court
District of New Jersey

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 1  BY MR. MARKETOS:

 2  Q.   Professor, did you look at one doctor, doctor by doctor,

 3  and cherry-pick one doctor out of the 5,000-plus doctors that

 4  you analyzed when you were performing your analysis?

 5  A.   No.

 6  Q.   All right.

 7       When we were looking at the studies of the behavior of

 8  these physicians who have been either marketed to by Janssen

 9  or had been paid by Janssen to be on the speaker bureau, were

10  you looking at one doctor or two doctors or three doctors or

11  thousands of doctors?

12  A.   If you were to see trend in prescribing behavior, you

13  don't take doctor by doctor.  You cannot see prescribing

14  behavior or trend by taking two or three.  Like, here, there's

15  328 at one visit.  That's almost 5,000 that got more than one

16  visit.  So I don't take any -- cherry-pick any one of them

17  individually.

18  Q.   And let's stop there for a second, if we could.

19       Ms. Brown was asking you questions like, well, your

20  entire model of damages is based upon a doctor receiving

21  Janssen's influence or receiving an off-label promotion the

22  first time they were contacted by Janssen.

23       Do you recall that?

24  A.   That's correct.

25  Q.   Or the first time they were paid a $2,500 check to speak
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1   at a speaking event.

2   Fair?

3   A.   That's fair.

4   Q.   Okay.

5   But how many of the doctors -- and I'm going to go

6   ahead and read this into the record, sir, so bear with me.

7   In Slide 56, you have broken down out of 5,177

8   physicians the number of marketing contacts that each of those

9   doctors had.

10   Do you see that?

11 A.   Not each doctor. Right.

12 Q.   Yes.

13   So if we take a look at marketing contact, I'm going to

14 start with Line Item Number 1 on the left, one marketing

15 contact, and then there's a number of influenced physicians.

16 That's only 328 physicians.

17   Do you see that?

18 A.   That's correct.

19 Q.   And that's 6.3 percent of the 5,177 doctors.

20   Right?

21 A.   Right. It's even the smaller percentage of the damages.

22 Q.   Yes, sir.

23   So it's a -- if you're talking about the amount of

24 damages allocated to doctors who only had one contact with

25 Janssen, what percentage of the damage that you calculated is

1 associated with doctors who only had one contact or one

2 payment from Janssen?

3 A.   It's a couple percentage. 1 or 2 or so.

4 Q.   1 to 2 percent?

5 A.   Yeah, that's it, because it -- it's 6.3 percent of the

6 physician, but this physician have less patients so they

7 prescribe less. So in terms of damages, they're about 1-plus

8 percent of the total damages.

9 Q.   The doctors who -- Professor Shaked, the doctors who only

10 got one contact, were they, generally speaking, small

11 community doctors who only had -- who didn't have a lot of

12 contacts with Janssen?

13 A.   What is the question?

14 Q.   Sorry.

15   The doctors who only had one marketing contact, were

16 those generally smaller practices and only had, like, limited

17 contact with Janssen?

18 A.   At least those -- I didn't do exact statistics, but the

19 6.3 were generally prescribing much less than the other ones

20 at the top.

21 Q.   So bear with me, sir. This is for our record.

22   Okay?

23   For the marketing contacts, one-plus marketing contact,

24 that's all 5,177 doctors.

25   Right?

1   A.   Correct.

2   Q.   Five-plus contacts, that's 4,439 doctors.

3   Correct?

4   A.   That's correct.

5   Q.   Ten-plus marketing contacts, 4,157 doctors.

6   Right, sir?

7   A.   Yes.

8   Q.   25-plus contacts, 3,680 doctors.

9   Right, sir?

10   A.   That's correct.

11   Q.   Sorry for making you go through this.

12   50-plus marketing contacts. 3,187 doctors had 50-plus

13   marketing contacts.

14   Correct?

15   A.   That's correct.

16   Q.   100-plus marketing contacts is 2,355 doctors.

17   Right?

18   A.   45 percent of the total, yes.

19   Q.   200-plus marketing contacts. 1,208 doctors had 200-plus

20   contacts.

21   Right, sir?

22   A.   Yes.

23   Q.   250-plus contacts. 876 influenced physicians.

24   Right, sir?

25   A.   That's correct.

United States District Court
District of New Jersey

 1 Q.   300-plus was 644 influenced physicians.

 2   Correct?

 3 A.   Yes.

 4 Q.   350-plus was 491 doctors.

 5   Right?

 6 A.   Yes.

 7 Q.   400-plus marketing contacts. That was 360 doctors with

 8 400-plus marketing contacts.

 9   Correct?

10 A.   That's correct.

11 Q.   500-plus marketing contacts was 201 doctors.

12   Right, sir?

13 A.   That's correct.

14 Q.   And a thousand-plus marketing contacts. 10 doctors

15 received more than a thousand contacts from Janssen.

16   Is that right?

17 A.   That's correct.

18 Q.   Is it a fair and accurate representation to state that

19 most people or most doctors only had one marketing contact

20 with Janssen?

21 A.   No, that's taking out of -- it's taken out of context.

22 That's what I said a few times. The 6.3 percent, you got one

23 contact. 19-plus percent got more than one contact.

24 Q.   Is that why you perform a statistical analysis and not

25 engage in a cherry-picking exercise?

1   A.   Right. I cannot go over 5,000 people like counsel did to

2   see a chart, the way I do it, because the way I do it is to

3   see how many contacts is this and is there any correlation

4   between the number of contacts and the prescriptions.

5   That's a better way to do it with statistics.

6   Q.   Thank you, Professor.

7   And again, just to remind everybody, the median, the

8   typical doctor that Janssen called upon or had contact with at

9   a speaking event, was 85.

10   Is that right?

11 A.   Right. That's the median.

12 Q.   Not one two, three, five, ten, or otherwise. 85 contacts

13 with Janssen's sales force.

14   Right.

15 A.   That's right.

16 Q.   Was this the sales force that Janssen's only marketing

17 expert determined was the most effective in the business?

18 A.   Right. The PILM, if you looked earlier, were extremely

19 impressed by these salespeople. They're right everywhere.

20 It's better than any other one we saw in the pharma industry.

21 Q.   And if we take a look at, sir, the average number of

22 contacts, that's 135 per doctor.

23   Right?

24 A.   Correct.

25 Q.   Now, if we could switch over to the ELMO, I'd like you to

United States District Court
District of New Jersey

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 1  explain, if you could, Professor Shaked:  How does this

 2  contacts and the number of doctors -- the assumption that you

 3  were asked to make, how does it bear into your analysis?

 4       Okay?

 5  A.   Okay.

 6  Q.   I'm going to see if I can show you this, and it's going

 7  to be a miracle if I get the focus -- yes.  I got it focused.

 8  Okay.

 9       So let's just explain this for the members of the jury.

10  When you were building your assessment to figure out how many

11  times a doctor -- excuse me -- to figure out how much money

12  was reimbursed by government payors --

13  A.   The damages.

14  Q.   Yes, sir, for the damages.

15       Did you have to start somewhere?

16  A.   Yes, obviously.  You need to start somewhere in a model

17  like that.

18  Q.   Now, as I understand it, what Janssen is saying, I think,

19  is that, Well, not every single salesperson says that they

20  delivered an off-label message every single time?

21  A.   Right.

22  Q.   Right, sir?

23       So -- and we can go through the testimony in a moment,

24  but does that -- that subject matter affect all of your

25  damages, or would it just affect when you started the damages
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 1   assessment, at contact number 1 or 2 or 3?

 2   A.   For my knowledge of the data, which I looked at quite

 3   many times, even if you move to the second and third one, you

 4   know, the impact could be very small.

 5   Q.   Okay.

 6        So if you were to have assumed that by the second

 7   visit --

 8   A.   Right.

 9   Q.   -- a Janssen sales representative or any other Janssen

10   sales representative had delivered an off-label message and

11   you were to move to the second contact in the data, how would

12   that affect the damages calculations that you've provided to

13   this jury?

14   A.   Very little.

15   Q.   Very little.

16        What if you chose the third contact, if you said --

17   well, let me give you an example.

18        I know you were promised a readback of the testimony,

19   but Ms. Brancaccio actually testified that she delivered an

20   off-label message from 2006 to 2014 almost every time.

21        Do you recall reading that testimony when you reviewed

22   the transcript?

23   A.   Very different from what I was told a minute ago.

24   Q.   Yes, sir.

25        Let me see if I can find it for you.  I've got lots.
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1 Bear with me. Here we go.

2   Ms. Christine Brancaccio -- "and correct me if I'm

3 wrong" -- this is trial transcript day -- May 20, 2024, Day 8,

4 line 21 -- 18.

5   "And correct me if I'm wrong, but I thought I heard

6 your testimony last week that it wasn't actually every single

7 call, right?

8   "I said almost every.

9   "Okay. It's just most calls now?

10   "I said almost every."

11   That's what Ms. Christina Brancaccio testified to.

12   Do you recall that? That's her right here on the

13 board.

14 A.   Yeah. I see her.

15 Q.   Okay.

16   Now, Mr. Wilhelm testified: "Did you hear off-label

17 presentations when you were at Tibotec?

18   "I did.

19   "Did you attend those?

20   "I did.

21   "How frequently would a physician who was speaking go

22 off label?

23   "ANSWER: The majority of the time."

24   Did you review that testimony?

25 A.   Yeah. That's what I said few times, but I heard

United States District Court
District of New Jersey

 1 different things from the -- from Ms. Brown.

 2 Q.   Yes, sir.

 3   Ms. Sara Strand, trial testimony: "And was that a

 4 practice that was limited to a couple of salespeople, or was

 5 that like district-wide for the eastern part of the company?

 6   "ANSWER: It was actually nationwide because all of the

 7 district managers across the entire company were getting this

 8 message pushed down to them to have their reps say these

 9 things. So it was disseminated across the entire company."

10   Did you review that testimony?

11 A.   I reviewed, and I was concerned with earlier that I have

12 some Alzheimer's because I read that once, and I got told that

13 "no," actually they didn't actually say anything.

14 Q.   And then with respect to Ms. Brancaccio in this lawsuit,

15 she said, again: "Nancy Bartnett, we were having a sales

16 call, and she always went off label in the conversation with

17 the physicians in my presence."

18   So even when -- when Ms. Brancaccio wasn't delivering

19 that message, Ms. Bartnett was according to her testimony.

20   Do you recall reviewing that?

21 A.   Yeah. I recall reviewing. My general recollection was

22 that people say almost or 80 percent and so on, but I must

23 have thought -- I was told before by Ms. Brown I did not

24 recollect as much, and I admitted I don't recollect.

25 Q.   Sure, sir.

United States District Court
District of New Jersey

1   Let's take a look at what Mr. Grooms testified to. He

2   was just with us last week.

3   "What were they telling you was happening in their

4   districts across the country?

5   "ANSWER: It was the same message. We wanted to get to

6   a certain -- get certain information out if we could.

7   "QUESTION: Can you estimate for us how many times

8   there was a plant asking off-label information in the

9   audience?

10   "ANSWER: From my events, would be every single one."

11   Do you recall that testimony from him?

12   A.   Absolutely.

13   Q.   He was asked: "Of all the doctors that you called on

14   during your time at Janssen, did they hear the off-label

15   messages that you discussed for Prezista and Intelence?

16   "ANSWER: Of all 35, it would be hard to say all, but I

17   would say everybody, at least 90, 95 percent, if I got a

18   chance to get in front of them, yes, I would cover the

19   message.

20   "You would cover the message with anybody who you got

21   in front of?

22   "Correct."

23   Do you recall reviewing Mr. Grooms's testimony from

24   last week, sir?

25   A.   Yes.

 1 Q.   And he even told us what the messages were that he

 2 would -- he would review.

 3   "Once-a-day dosing was one of the hot topics, so that

 4 was always coming up. It was always in the air."

 5   Do you recall reviewing that?

 6 A.   Yes.

 7 Q.   Mr. Grooms: "So I would always have to go prep either a

 8 pharmacist or doctor or nurse to make sure they asked one or

 9 two of these questions to get to the information that we

10 wanted to get out."

11   Do you recall Mr. Grooms testifying to that about the

12 plant that would be placed in the audience at the speaking

13 events?

14 A.   The shields, the ones that you ask them to ask questions

15 you talk about, right? Yes.

16 Q.   "Ms. Penelow, and you had the opportunity to go on many

17 sales rides and sales calls with Ms. Bartnett. Did she

18 frequently sell to doctors that it was lipid friendly from

19 2006 to 2013 when you left?

20   "Most of the time."

21   Do you recall that testimony?

22 A.   This is a very general impression of my recollection --

23 general recollection of my impression -- sorry -- from reading

24 testimony that many people say almost every time, 70, 80

25 percent.

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 1          It was clear to me that that's what people testify

 2   about.

 3   Q.   And then an answer from Ms. Penelow:  "Your testimony now

 4   here in this courtroom is that despite all this testimony,

 5   that pressure, and the forecasts you weren't promoting off

 6   label in 2006?

 7          "ANSWER:  I personally wasn't, but Frank Murphy and

 8   Nancy Bartnett were."

 9          Do you recall reading that testimony?

10   A.   Yes, and I think -- I was told that she didn't work in

11   2006.

12   Q.   Answer --

13          "QUESTION:  Are you sure that a hundred percent of the

14   doctors -- not the number of calls or visits to the doctor,

15   but a hundred percent of doctors that you called on heard

16   off-label messages?

17          "ANSWER:  Yes, I am."

18          Sir, was it an accurate representation of the trial

19   testimony that was presented to you by Janssen's counsel

20   during your cross?

21   A.   You put me in the corner.  I definitely don't want to use

22   strong words, but this testimony that I hear now and what I

23   heard 20 minutes ago, it's a day and night.  I mean, people

24   like to take things out of context.  That's not unusual.

25   Q.   Okay, sir.
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United States District Court
District of New Jersey

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 1          Let me ask you this other question.  You were also

 2  asked a question about whether or not minimizing side effects

 3  is off-label promotion of a drug.

 4          Do you recall answering questions about that?

 5  A.    Meaning side effect.

 6  Q.    Yes.  The minimization of -- as I understood, is not off

 7  label if you minimize a side effect that's on the label.

 8          Do you recall answering questions about that from

 9  Ms. Brown?

10  A.    I don't even remember, because I know nothing about

11  minimizing side effect.

12  Q.    And I'm just showing you the testimony from the former

13  president of the company.

14  A.    Right.  I was -- I was here when he testified.

15  Q.    And he gave to the members of the jury the following:

16          "QUESTION:  You've got adverse effects on a label.  Any

17  promotion that minimizes those effects or promotes those

18  effects as not existing, that's off-label promotion."

19  A.    Yes.

20  Q.    "ANSWER:  Yes."

21          Were you present for that testimony from

22  Mr. Glenn Mattes?

23  A.    Yes.

24  Q.    All right.  We can go back, if we could, to the slides.

25          You were asked some questions about CMS continuing to
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1 pay.

2   Do you recall that, sir?

3 A.   Yes.

4 Q.   And you're not here as a CMS expert, but it's the

5 Department of Justice or other agencies that have taken

6 enforcement actions against companies that have been paid and

7 received money from the federal government for off-label

8 promotion.

9   Correct?

10 A.   That's correct.

11 Q.   All right.

12   Is it your understanding that this lawsuit is being

13 brought on behalf of the federal government by the Relators?

14 A.   I believe that most, if not all, anti-kickback and false

15 claims that I was working, either the government joined as a

16 party or did not join but was involved also.

17 Q.   And let's look at RX-275.

18   MR. MARKETOS: If we could switch to that, please,

19 Ms. Johnson. Thank you. We're going to go to page 7 of

20 Relators' Exhibit 275. Thank you.

21   This is a Janssen document that has been shown to the

22 members of the jury. Let's go ahead and pull this up.

23 BY MR. MARKETOS:

24 Q.   "The government does not want to cover the cost of

25 prescription products when they violate the following:

United States District Court
District of New Jersey

1   Anti-Kickback Statute, False Claims Act."

2   Are you calculating damages consistent with what

3   Janssen and Johnson & Johnson told their own employees, that

4   the government does not want to cover the cost of these

5   products if they violate the Anti-Kickback Statute or the

6   False Claims Act?

7   A.   Yeah. I -- I -- basically my damages include all the

8   amounts that -- anti-kickback, all the amounts that were

9   prescribed by the doctors that fall under this umbrella.

10   MR. MARKETOS: And let's just take a look at the

11 bottom -- right there, please, Ms. Johnson, the notes.

12 BY MR. MARKETOS:

13 Q.   "Government does not want to cover the cost of

14 prescription products when they violate the following:

15 Anti-Kickback Statute, exchanging anything of value in return

16 for business, the False Claims Act, selling off label, or

17 making misrepresentations about a product."

18   Right, sir?

19 A.   Yes.

20 Q.   Okay.

21   Are the damages that you calculated specific to claims

22 of off-label promotion of Janssen's drugs and the payment of

23 kickbacks to doctors?

24 A.   Yes.

25 Q.   Is it your understanding, sir, that the focus of the

United States District Court
District of New Jersey

1 Anti-Kickback Statute is not on the doctor and what he or she

2 thinks about whether they were influenced --

3   MS. BROWN: Objection, Your Honor.

4   THE COURT: Sustained.

5   MR. MARKETOS: Fair enough.

6 BY MR. MARKETOS:

7 Q.   Let me rephrase that, sir.

8   When you were looking at the kickbacks or calculating

9 damages associated with kickbacks, were those associated with

10 payments that were made by Janssen to doctors?

11 A.   The amount -- the amount -- the correct amount that I

12 would say is the amount the government paid Janssen, not --

13 Janssen and the doctors is a different part of flow of cash.

14 The cash is the focus of my -- you know, my experience with

15 these cases is how much the government took out of the pocket,

16 not how much Janssen paid to the speaker.

17   That's really the part.

18 Q.   And you were able to analyze the amount that Janssen paid

19 to the speakers to look at their behavior after they got paid.

20   Do you recall that?

21 A.   Correct, but that's not part of my damages calculation.

22 Q.   The focus of the damages is on the amounts that Janssen

23 received ultimately from reimbursements from the government

24 payors.

25   Right?

United States District Court
District of New Jersey

1 A. Absolutely every one of the anti-kickback or a few of

2 them -- I didn't work on many of them, but quite a few -- all

3 of them focused on the same thing.

4 Q. You were shown the top two doctors -- there were two

5 doctors that were pulled out who apparently received contact

6 from Janssen but did not prescribe off label, as I understand

7 it.

8   Do you see that?

9 A. No, no. It's an influence that got many, many calls and

10 did not prescribe, right?

11 Q. Yeah, I think that's what I saw.

12   But I'm going to remind you about Dr. Peredo and

13 Dr. Matthews, somebody different. They were -- they pulled

14 two doctors out and showed that -- their rates of off-label

15 prescription.

16   If a doctor couldn't be matched up with an ID number,

17 were they included in your damages calculation because you

18 couldn't figure out who it was?

19 A. No.

20 Q. So you excluded them?

21 A. If I didn't have an exact relationship between the doctor

22 and the physician, I didn't calculate it. I included it in

23 the -- in the off-label analysis and so on.

24   For example, as I said in my testimony, Medicaid, about

25 34 percent or 390,000 to 1.1 million, I didn't have the

1   details necessary, so we just left it out.

2   Q.   And, sir, maybe if we could look and see if Dr. Peredo

3   who was referenced went to some of these steak dinners, and he

4   might show up on that list.

5   But until we get there, if you couldn't match them up

6   with a national payor identification number, did you take them

7   out of your damages analysis?

8   A.   Absolutely.

9   Q.   Okay.

10   What is the point of using statistics for large bodies

11   of data? Is it to focus on outliers or to demonstrate

12   mathematical and statistical trends?

13   A.   Statistics, you know, we all live and die by these

14   statistics, unfortunately, and the reason I bring it --

15   example, every election day, you look at the television and

16   say, We believe that Michigan would be won or lost or whatever

17   based on 1,200 people. And you ask yourself, Wait a minute.

18   Based on 1,200 people, they now know things about the entire

19   state?

20   With appropriate methodologies you can actually get

21   some accuracy. Now, lucky in this case, I don't have 1,200

22   people. I have 75,000 patients of the influence, and 38,000

23   of the non-influence, so the body really tells you about

24   prescribing trend and behavior, not individually every doctor.

25   I don't -- here to say our doctor really prescribed.

United States District Court
District of New Jersey

1 That's not the story.

2 Q.   There are 5,177 physicians that had some type of

3 marketing contact or influence from Janssen.   I suppose we

4 could call all 5,177 doctors individually one at a time to the

5 witness stand, and this trial might go on for 15 years.

6 A.   Go ahead.   The jury would be called in 2030.

7 Q.   But instead you -- instead you presented a statistical

8 analysis that supports the estimates to a reasonable degree of

9 certainty?

10 A.   It's like I say with the grades and the hours, not every

11 student that doesn't prepare gets a lousy grade, but this

12 methodology of getting relationship really works well, and I

13 always told the counsel one example I want to ask about

14 statistics.

15   I work many years ago on the tobacco litigation.   For

16 that case, all the cigarette companies say they only

17 correlation, there's not causation.

18   MS. BROWN: I object, Your Honor.

19   THE COURT: What's the basis?

20   MS. BROWN: The reference to the -- can we approach

21 at sidebar, Your Honor.

22   THE COURT: Sure.

23   (Sidebar begins at 2:23 p.m.)

24   THE COURT: Yeah, I just want to understand the

25 basis.

United States District Court
District of New Jersey

 1   MS. BROWN: He's about to say where, like, the

 2   tobacco industry denying that there was a correlation where

 3   they live -- it's an inflammatory --

 4   THE COURT: Is that what he was going to say?

 5   MS. BROWN: -- example. Yes.

 6   MR. MARKETOS: I think he's saying, in response to

 7   her suggestion that correlation is not causation, that he

 8   worked on the tobacco cases and they said correlation was not

 9   causation.

10   MS. BROWN: It's highly prejudicial, Your Honor, and

11   inflammatory.

12   THE COURT: How is that coming out?

13   MR. MARKETOS: I don't know, but I can rephrase it

14   and make sure it doesn't.

15   THE COURT: Rephrase it and make sure it doesn't.

16   MR. MARKETOS: Okay. Understood. But correlation to

17   causation is what he was talking about.

18   THE COURT: Not if he's going to connect it to

19   tobacco litigation. What's next? I mean, you know what I

20   mean?

21   MR. MARKETOS: I do.

22   THE COURT: Like, let's be careful about not

23   connecting -- because I think that's an unnecessary

24   connection.

25   MR. MARKETOS: I agree.

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 1              THE COURT:  So all right.  The objection is

 2   sustained.  Are you rephrasing the question?

 3              MR. MARKETOS:  I'm going to ask a different one, if

 4   that's okay, just a different topic.

 5              THE COURT:  Yeah.  Let's get off of that.

 6              MS. BROWN:  Can we strike his answer?  He said it's

 7   like the tobacco industry.

 8              THE COURT:  Yeah.  I'm going to strike the reference

 9   to tobacco litigation.

10              MR. MARKETOS:  Well, let me be -- let me be clear

11   about this.  I'm avoiding it for the concerns that Your Honor

12   is raising.  But the correlation/causation argument that

13   they're making in this case was that argument that they made

14   for that case.

15         And he worked on it, and it ultimately was determined

16   causation.  I'm staying away from it because I don't --

17              THE COURT:  You can't litigate in some prior case

18   because then what will happen is we're going to have to get

19   into.  But what was the same or different about that case?

20              MR. MARKETOS:  Yeah, I get it.

21              THE COURT:  So let's stay away from --

22              MR. MARKETOS:  I get it.

23              THE COURT:  -- analogizing to another case.

24              MR. MARKETOS:  I'm going to move to another topic

25   right now.  Is that okay?
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1   THE COURT: Yeah. So can I just strike the response

2   because we're moving on anyway?

3   MR. MARKETOS: Sure.

4   THE COURT: Let's move on.

5   (Sidebar was concluded at 2:25 p.m.)

6   (Open court.)

7   THE COURT: Hey, folks. I'm just striking the last

8   question and response. We're going to move on to a different

9   topic.

10   I want to make sure to the extent you were listening to

11 that last response, it's not to be considered.

12 BY MR. MARKETOS:

13 Q.   I wanted to ask you, Professor, about this notion that a

14 physician who is influenced makes a prescription and then all

15 the subsequent prescriptions for Prezista or Intelence are

16 included in damages to the government.

17   Okay, sir?

18 A.   Okay.

19 Q.   Now, did Dr. Glatt himself provide you the parameters

20 associated with this whole concept of the lipid issue for

21 Prezista?

22 A.   Yeah. I never talked to him directly. I asked the

23 question, you provided him the question, you got the response

24 and you forwarded it to me.

25 Q.   And you were present for his testimony in this courtroom

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 1   to the members of the jury that he looked at the assumptions

 2   clinically and determined that they were medically sound.

 3         Do you recall that?

 4   A.   Correct.  Absolutely.

 5   Q.   Okay.

 6         But Dr. Glatt also explained the concept of a

 7   continuing prescription.  So a patient who was prescribed

 8   Prezista or Intelence by a doctor influenced by Janssen and

 9   subsequent doctor keeping them on the same drug.

10   A.   You call it "attributed."  The second one is attributed

11   to the first.

12   Q.   Yes.

13         MR. MARKETOS:  If you could switch to the ELMO for

14   me, please, Ms. Johnson.

15   BY MR. MARKETOS:

16   Q.   Dr. Glatt testified, and I'm going to read this because

17   there's a glare.

18         "So when there's a switch and a second doctor

19   reassesses the first doctor's prescription, in most cases, are

20   they going to leave the patient on the exact same drug as long

21   as there's no resistance issues?

22         "ANSWER:  If I was being referred a patient that

23   another doctor had seen and they're doing well on that

24   regimen, usually you will not touch that regimen.  You'll

25   leave them on what they're on.  We're loathe to switch people
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 1 | that are doing well on HIV, especially during the relevant

 2 | period of time. If somebody's doing well, don't touch it.

 3 | "The general rule of thumb was don't play games. If

 4 | they're doing well, let them be."

 5 | Do you see that?

 6 | A.   Yeah, of course. I still remember it.

 7 | Q.   And was that part of the assumption that you were asked

 8 | to make in assessing damages to the government?

 9 | A.   This is exactly what I told Ms. Brown. I remember that

10 | Glatt said that you rarely change. You can change, obviously,

11 | but it's only rarely happening.

12 | Q.   And then there's questions by counsel from Janssen for

13 | Mr. Sillup, Professor Sillup.

14 | "This concept of Prezista and Intelence, as I

15 | understood it, there was a statement made, if it ain't broke,

16 | you don't fix it.

17 | "Right, sir?

18 | "Yes."

19 | And then from my question:

20 | "And that's actually something Dr. Glatt testified

21 | about. He was testifying about if a patient is doing well on

22 | the drug and they even switch doctors, there's a likelihood

23 | that the doctor won't switch them off that drug.

24 | "Right, sir?

25 | "ANSWER: Yes."

United States District Court
District of New Jersey

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 1        Was that the assumption that you included as part of

 2   your assessment of damages to the government with a reasonable

 3   degree of certainty?

 4   A.   This is the assumption, and I think you work too hard.

 5   The same assumptions was written, at least in paragraph 40, of

 6   Janssen's expert report.  You say they rarely change.  There

 7   is a tendency to continue.

 8   Q.   And we can ask Janssen's expert that same question when

 9   he arrives.

10   A.   Yeah.

11   Q.   Okay.

12        You were asked about the national strategy for HIV/AIDS

13   and getting patients unfettered access to HIV drugs.

14        What does that have to do to your analysis and whether

15   or not drugs have been prescribed after payment of kickbacks

16   or for off-label promotion?

17   A.   This question can't be from left field.

18   Q.   Okay.

19   A.   I have no idea about the national strategy.  It's not my

20   job, and this is totally irrelevant to my opinion, definitely.

21   I didn't understand why the question was asked.

22   Q.   What does it have to do with an assessment as to whether

23   or not kickbacks were paid or off-label promotion was taking

24   place in order to have those drugs prescribed to begin with?

25   A.   Absolutely nothing.
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United States District Court
District of New Jersey

1 Q.   If we take a look, sir, at -- one second.

2   Sir, is it necessary for your damages model that all

3 doctors who received Janssen's marketing prescribed off-label,

4 or was it the statistics showing the rate of their prescribing

5 off-label that you looked at?

6 A.   Well, one of the mistakes that people are making in

7 statistics, and you will see it in a few days when another

8 expert will come, he has tables talking about the count, the

9 number of. The number of is misleading. If somebody has a

10 lot of patients, the other one is few, the measure is what

11 proportion of their prescription they do off-label.

12   Somebody has 100 patients and 30 of his people are

13 off-label, it's much more than somebody has only 10 and 1. So

14 the rate is really important. So the rate of prescribing

15 off-label is the appropriate measure.

16 Q.   Thank you, Professor.

17   Are you aware -- were you able to look at Dr. Hsu

18 himself and learn that he actually prescribes off-label for

19 these drugs 49 percent of the time?

20 A.   I don't remember the number, but I know it was very high.

21 Q.   You were asked some questions about a Dr. Scott Hoskinson

22 and Dr. Barbara Beard.

23   Do you recall that -- do you recall answering some of

24 those questions from Janssen's Dr. Scott Hoskinson and

25 Dr. Barbara Beard?

United States District Court
District of New Jersey

1   Those were some doctors she showed you.

2   Do you recall that?

3   A.   I remember the question. I don't remember the names.

4   Q.   Okay.

5   Again, just one last time. If we looked through the

6   data at 5,177 doctors, could you find an anomaly here or

7   there?

8   A.   Absolutely. You find anomaly in any group of

9   observation, whether it's 300 doctors, 100 students, if they

10 have in the classroom, there's always some anomaly. And the

11 statistic, basically, is not to deal with every single

12 individual case. It is to deal with a trend and observe

13 behavior.

14 Q.   How was your assessment of damages conservative at the

15 end of the day? Can you give us some examples of how you've

16 taken into account potential anomalies here and there and

17 adjusted downward the number that you're asking for Janssen to

18 reimburse the government?

19 A.   As I said early on, and I mentioned it already twice

20 maybe, I say it now, I list the conservative. Medicaid is not

21 very good in keeping data. Medicare is fantastic. Medicare,

22 we have 98-point-something percent of perfect matching.

23   Medicaid, I have, as I say, only 65 percent of

24 matching. About 30-plus, I didn't have.

25   So when I did analysis of off-label, I left out all the

United States District Court
District of New Jersey

1 390,000.

2   Now, you think about the 390,000, and you multiply it

3 by $700 per 90-day prescription, that's $700. You talk

4 about -- I don't know in my head, but this would be

5 approximately over $200 million just prescription that I left

6 out, not off-label, but prescription.

7   So I decided -- and in consultation, obviously, with

8 the data guy, I asked him, Don't do anything; that we are not

9 100 percent sure that they have a relationship.

10 Q.   So you've got 97-or-so percent of data from Medicare, and

11 you've got only 65 percent of usable data from Medicaid.

12 A.   Correct.

13 Q.   And so what did you do with the other 35 percent?

14 A.   What I do is I still -- still in the computer. I didn't

15 touch them, decided not to use things that I not --

16 Q.   Okay.

17 A.   As a statistician, you have to know that there's some

18 point that it's not even worthwhile trying to use information

19 which is not clean. You can estimate, but use information

20 that is not perfect it's going to really come back to haunt

21 you.

22 Q.   Now, were you able to make some estimates with data that

23 you obtained from pharmacies in order to determine issues

24 relating to dosage?

25 A.   Correct. The reason I mentioned it, five years ago, I

United States District Court
District of New Jersey

1   was in the position, and it's not possible, and somebody else

2   asked me, Are you sure that 300,000 prescription from the

3   three pharmacies representative? This is word by word

4   question that I was asked.

5   And I look at the person, I say, look, I do statistics

6   for almost 50 years by now. Since 1973. 300,000 is a luxury.

7   Not every day I have 300,000 numbers that I can't really use

8   to estimate something.

9   So I didn't need everybody who goes to a Walgreen or

10   CVS. I have 290,000 from Walgreen, another one from Rite Aid,

11   another 40 plus 6,000, another 29,000 from, what -- from

12   BioScrip, so about 300,000 numbers.

13   It's enough to estimate the -- the daily versus twice a

14   day issue, which is related to this case.

15   Q.   Okay.

16   When given the size of the data, were you able to

17   accurately estimate the QD dosage issue?

18   A.   Absolutely. As I said, 300,000 is not every day. I have

19   so much information.

20   Q.   And with respect to ADAP, Ms. Brown asked you, okay,

21   you've got Medicare, Medicaid and ADAP. And ADAP was

22   aggregated. It was information that came in one big lump sum.

23   Right, sir?

24   A.   Correct.

25   Q.   How were you able to use statistics and econometric

United States District Court
District of New Jersey

1   methods to estimate the reimbursement that would be due from

2   the ADAP program?

3   A.   Well, I worked together with Ian. Together we worked on

4   the problem with my team, obviously.

5   Turn out that add up, we have total amounts, we have it

6   by quarter, and we don't have the relationship with the

7   doctors. So at least I could estimate some of it from

8   Medicaid. Turn out that -- he showed me the fields. The

9   fields for Medicaid and ADAP are very similar. So what we

10 did, we did take the same proportion that we found in Medicaid

11 and apply some of them to ADAP.

12   Now, why is it conservative? Remember that I lost

13 two-thirds of the numbers on Medicaid. So it's also lower, my

14 damages, so I'm added, because I have to use a small number.

15   So Medicaid and ADAP are similar in the nature of the

16 ways -- the ways they actually collect or expended it. Like,

17 one is 100 field, the other one is maybe 60 or 70 field for

18 every prescription.

19   So I said, okay. Let's take a look at that one. See

20 the proportion in Medicaid and use it in ADAP. It's not

21 really a very rough estimate because the probabilities appear

22 to be mistake is very, very small. A, we left about $200

23 million of prescription in Medicaid. And the second one, the

24 nature of these two are highly similar.

25 Q.   And given the size of the body of data that you had

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 1  available to you, the amount of claims and the size of the

 2  body of data that you had available to you, were you able to

 3  make those estimations for ADAP to a reasonable degree of

 4  certainty?

 5  A.   Yeah.  I still -- even though I lost one-third of

 6  Medicaid, I still had about 600,000 claims in Medicaid, out of

 7  the 900-plus.

 8  Q.   Sir, we're close to finishing.

 9       MR. MARKETOS:  Can we take a look at Relators'

10  Exhibit 149, please.

11  BY MR. MARKETOS:

12  Q.   And if you would, when you get there, let's turn to

13  page 29.

14       This is something that's in evidence was discussed with

15  Mr. Mattes.

16       If we turn to page 29, there's a value of a Prezista

17  patient calculation.

18       Do you see that, sir?

19  A.   Yes.

20  Q.   And what we have here is a lifetime value undiscounted

21  and discounted.

22       Do you see that, sir?

23  A.   Right.

24  Q.   And there's information presented on this -- on this

25  slide that has to do with how much money a patient is worth in
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1 dollars.

2   MS. BROWN: Your Honor, I object as mischaracterizing

3 the document and argumentative.

4   THE COURT: Sustained.

5   Rephrase, Mr. Marketos.

6   MR. MARKETOS: Sure. Thank you.

7 BY MR. MARKETOS:

8 Q.   Do you see the lifetime value of an undiscounted

9 prescription value of a Prezista patient calculation?

10 A.   Yes, I see.

11 Q.   Okay.

12   Is this what you were talking about when you said, I

13 cut it off at 2014 but I would have expected there to be more

14 damage beyond that time period?

15 A.   Absolutely.

16 Q.   Were you given those parameters because the time period

17 that we're discussing in this case is from 2006 to 2014?

18 A.   Yes. I didn't know the legal reason for this. I was

19 asked, and I said, frankly, I say, I don't know. I never

20 asked -- I rely on you guys.

21 Q.   Something to do with the case --

22 A.   Okay.

23 Q.   -- and the law.

24   Okay?

25 A.   Okay.

United States District Court
District of New Jersey

1   Q.   All right, sir.

2   At the end of the day, you did not continue to

3   calculate damages beyond 2014.

4   Is that fair?

5   A.   This one I mentioned more than once. The big money is --

6   fortunately for us, if people get today this HIV and some

7   varieties, the life expectancy of the time of the case was,

8   like, 71 already. Quite, quite significant.

9   So if you are put on Prezista, maybe Prezista would be

10 replaced by some other thing at some point, but it doesn't

11 make sense if everybody stop consuming it in 2014. At least

12 some people were under it -- or after it.

13   I didn't take any of that into account based on

14 discussion with the counsel and say, Let's leave it out. But

15 that's definitely conservative because there is a value --

16 it's like an annuity. Once you get them there, you're a

17 lifetime. People who take anticholesterol, the same thing.

18 It's, you know, a lifetime kind of thing. You don't get off

19 it.

20 Q.   And finally, Professor Shaked, you were asked some

21 questions about an issue that was brought up. Ms. Brown was

22 talking about, look, these doctors, I think the 5,177

23 influenced physicians, they are, as I understood it, more

24 expert. They're a higher grade of type of doctor, infectious

25 disease experts and the like. So they are not good

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 1  comparisons to make with other doctors in the nation.

 2       Did you generally understand that line of questioning?

 3  A.   Yeah, of course I understand it.

 4  Q.   Okay.

 5       Did you, when that issue was raised by Dr. Jena, did

 6  you perform an additional study to determine if that was an

 7  accurate characterization; that is, to make sure that your

 8  comparison was still sound regardless of any infectious

 9  disease-related issue?

10  A.   I wanted to see whether the bar chart that you saw today

11  can be affected by the specialty of the doctor.  So when I got

12  their -- Janssen's expert report, and you say, You didn't take

13  into account that most of the influence are expert in

14  infectious disease and most of the uninfluenced are not, I

15  said, Fine.  What I do in a case like this, I delete.

16       We went, obviously, on the national listing of doctors,

17  and one uninfluenced, we deleted anyone that didn't have the

18  code of infectious disease expert.

19       So I kept my -- my size small, all the

20  uninfluenced-only infectious disease versus the influenced

21  that Janssen said that they're already expert.

22  Q.   Wait.  Let me stop you there, Professor.

23       So you ran your statistical models again against only

24  infectious disease doctors who are not influenced by Janssen's

25  marketing and the body, 5,177 Janssen-influenced doctors.
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1 A.   Right.

2 Q.   And you did it -- and you performed your statistical

3 analysis a second time.

4   Is that right?

5 A.   Second time not because I found mistake. Because of the

6 challenge that came from their expert. I say, If I'm

7 challenged, I like to test it.

8 Q.   And what were the results of that test? Did it show that

9 your initial model was wrong, or did it confirm your initial

10 model?

11 A.   It's confirmed that you still see prescribing behavior

12 correlated with number of contacts and compensation. Not by

13 the identical, that's different doctors, but still, the same

14 thing you've seen before still holds. The more you get paid,

15 the more you prescribed -- not necessarily because of the pay,

16 I'm not here to opine on it -- and the more contacts you have,

17 the more way you prescribed.

18 Q.   And did those trends, with the prescribers' prescribing

19 habits, were they consistent throughout your studies that, the

20 more contacts that Janssen's marketing department had with

21 those doctors, the more they prescribed Prezista and Intelence

22 off-label?

23 A.   There was no one analysis that they performed that they

24 show flat or declining. Only going up. The more money you

25 have, the more prescription you have. The more contacts you

1 have, the more prescription you prescribe.

2 Q.   No matter which way you cut the data, no matter which way

3 you parse the data, no matter which statistical test you

4 perform, were those prescribing trends the same? The more

5 money that Janssen paid a doctor, the more he prescribed

6 Prezista and Intelence?

7 A.   Unless you arbitrarily eliminate part of the people

8 there, that the Janssen expert did, you get always the same

9 result.

10 Q.   And the more times that Janssen's marketing contacts

11 occurred, the more times Janssen had marketing contacts with

12 the doctor, they prescribed more Prezista and Intelence

13 off-label, was that consistent throughout your studies?

14 A.   Absolutely.

15   MR. MARKETOS: Thank you, Professor. Nothing

16 further.

17   THE COURT: All right, sir. You are excused from the

18 trial. Thank you.

19   THE WITNESS: Geez. What I'm going to do the rest of

20 my life?

21   THE COURT: I don't know.

22   Mr. Marketos, what is next?

23   MR. MARKETOS: Your Honor, we're obviously going to

24 reserve closing based on what we discussed, reserve resting

25 based upon Ms. Kaucher.

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 1            THE COURT:  All right.  You rest the case but with

 2   one consideration.  So you may complete your examination of

 3   Ms. Kaucher later in the trial.

 4            MR. MARKETOS:  Yes, Your Honor.  And introduce

 5   exhibits --

 6            THE COURT:  In that examination.

 7            MR. MARKETOS:  Yes, Your Honor.

 8            THE COURT:  Understood.

 9            MR. MARKETOS:  Thank you.

10            THE COURT:  Ms. Brown, are you all ready to proceed

11   with some presentation?

12         If so, can we take our short break now before you

13   reboot?

14            MS. BROWN:  Yes, subject to Mr. Wyatt needs to put

15   something on the record.

16            MR. WYATT:  Subject to this morning, we reserve on

17   our motions, both of the ones we talked about before court

18   today.

19            THE COURT:  Understood.  Yep.

20         All right, folks, let's take a ten-minute break, and

21   then we'll hear from Janssen -- beginning Janssen's

22   presentation on the defense.

23            THE DEPUTY COURT CLERK:  All rise.

24         (Jury exits the courtroom.)

25            (A short recess occurred.)
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United States District Court
District of New Jersey

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 1            THE DEPUTY COURT CLERK:  Please remain seated.

 2            THE COURT:  Ms. Brown, are we ready?

 3            MS. BROWN:  We are, Your Honor.

 4            THE COURT:  Who is the witness?

 5            MS. BROWN:  Ms. Megan McGrath is here.  Should we

 6  have her take the stand?

 7            THE COURT:  No, no.  Let's call her because she is

 8  not on yet.

 9            MS. BROWN:  Okay.  Yep.

10            THE COURT:  Yeah, I like to do it.  Otherwise, the

11  jurors get confused, did they miss testimony.

12            MS. BROWN:  Yep.

13            THE COURT:  Kim, you want to grab them?

14            THE DEPUTY COURT CLERK:  All rise.

15         (Jury enters the courtroom.)

16            THE COURT:  All right, folks.  Everybody have a seat.

17         Ms. Brown, are you ready to proceed?

18            MS. BROWN:  We are, Your Honor.  Janssen calls

19  Ms. Megan McGrath to the stand, please.

20            THE COURT:  Okay.  I'm going to have you sworn in

21  before you begin your testimony.

22  (**MEGAN MCGRATH**, HAVING BEEN DULY SWORN/AFFIRMED, TESTIFIED AS

23  FOLLOWS:)

24            THE DEPUTY COURT CLERK:  Please state your name and

25  the spelling of your last name for the record.
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United States District Court
District of New Jersey

1   THE WITNESS: Megan Elizabeth McGrath, M-C-G-R-A-T-H.

2   THE COURT: You may.

3   MS. BROWN: Thank you, Your Honor.

4 (DIRECT EXAMINATION BY MS. BROWN:)

5 Q.   Good afternoon, Ms. McGrath.

6 A.   Good afternoon.

7 Q.   Welcome to our trial. We are happy to have you here.

8   Would you start, please, by introducing yourself to our

9 jury.

10 A.   Sure.

11   Megan McGrath. I've been with J&J for a little under

12 12 years now in various HR roles of increasing responsibility.

13   I currently live in Virginia Beach, Virginia.

14   My first role at J&J was supporting Janssen

15 Therapeutics field sales for about a year and have since moved

16 on into other HR roles since then, including my current role,

17 head of compensation for enterprise functions and

18 Asia-Pacific.

19 Q.   So, Ms. McGrath, we're going to talk a little bit today

20 about a role you had a very, very long time ago at Janssen.

21   But could you start just giving us a little background

22 on your education and how you made it to Janssen, to start

23 off, in the beginning?

24 A.   Sure.

25   So I did my undergraduate degree in Washington, D.C.,

United States District Court
District of New Jersey

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 1  worked as a government consultant there for about four and a

 2  half years before going back to school to get my MBA and

 3  switch careers and industries, which led me to HR and health

 4  care and joining J&J.

 5       I joined through their HR leadership development

 6  program, and my first year-long rotation was supporting the

 7  Janssen Therapeutic field sales.

 8  Q.  And for purposes of our case, the time period is 2006 to

 9  2014.  It sounds like you would have been in your HR role in

10  about 2012.

11       Is that right, ma'am?

12  A.  Correct.

13  Q.  Okay.

14       And tell us what roles and responsibility you had in

15  that roll back in 2012.

16  A.  So day-to-day HR support for our field sales force, which

17  could have been working on HR strategies tied to performance

18  and development, succession planning, fielding employee

19  complaints or concerns, helping with coaching and mentorship

20  programs.

21  Q.  We have heard a little bit about you in this trial

22  already, Ms. McGrath, through some meetings that Ms. Penelow

23  testified she had with you.

24       Do you recall Ms. Penelow?

25  A.  I do.
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United States District Court
District of New Jersey

1 Q. All right.

2   And we have listened to a meeting that Ms. Penelow had

3 with you that was recorded in the fall of 2012.

4   Do you have a memory of meeting with Ms. Penelow in

5 person?

6 A. I do.

7 Q. All right.

8   And about that time frame, the fall of 2012?

9 A. Yes.

10 Q. Okay.

11   I want to play a couple of clips from that meeting and

12 ask you about what went on there, if that's okay, ma'am.

13 A. Sure.

14 Q. First of all, let me ask you --

15   MS. BROWN: Could we play video clip number 1,

16 Your Honor? This is already in evidence.

17   THE COURT: You may.

18   (Video clip played at this time.)

19 BY MS. BROWN:

20 Q. Ms. McGrath, that was -- we saw a clip of you there.

21   Is that right, ma'am?

22 A. Correct.

23 Q. And we saw Ms. Penelow's phone recording you as it got

24 slipped into her purse.

25   Did you see that?

1 A.   I did.

2 Q.   Did you know that this meeting that you were having with

3 Ms. Penelow was being recorded, ma'am?

4 A.   I did not.

5 Q.   Okay.

6   What's your reaction to learning that?

7 A.   A little traumatizing. It felt violated, to be honest.

8 Q.   Okay.

9   Ms. Penelow did not tell you she was recording the HR

10 meeting with you.

11   Is that fair?

12 A.   No -- that is fair.

13 Q.   She didn't ask for your permission.

14   Is that fair?

15 A.   Correct.

16 Q.   All right.

17   I want to talk to you a little bit about what it is

18 that you discussed with Ms. Penelow there.

19   MS. BROWN: Could we play video clip number 2,

20 please.

21   (Video clip played at this time.)

22 BY MS. BROWN:

23 Q.   Ms. McGrath, do you have a memory of Ms. Penelow raising

24 some of these concerns about her return from disability in the

25 New York district?

1 A.   I do.

2 Q.   And do you remember Ms. Penelow talking to you about a

3 number of different things that she was unhappy with at that

4 time?

5 A.   I do.

6 Q.   Is that part of your job, ma'am?

7 A.   In terms of employee conflict with their manager, yes.

8 Q.   Right.

9   Is it part of your job, Ms. McGrath, to make folks kind

10 of feel comfortable about coming to you with any concerns or

11 complaints they might have?

12 A.   Yes.

13 Q.   And we heard a couple of complaints here about

14 Mr. Fernandez and getting back to work after disability.

15   Do you have a general memory of the types of things

16 Ms. Penelow was upset about or relating to you during this

17 meeting?

18 A.   Yes.

19 Q.   And what do you recall about that, ma'am?

20 A.   I remember what the recording had said. She felt like

21 she wasn't valued by the team. I remember we talked about --

22 she raised she has her MBA, felt like she should be putting it

23 to better use. I had just graduated with my MBA, so we talked

24 about that, how sometimes you don't always get to be assigned

25 to projects you think you might be qualified for.

United States District Court
District of New Jersey

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 1        I listened as she talked about other concerns she had
 2   with her current manager, Tony Dolisi, and tried to help her
 3   think about how we could get her back to work like she wanted
 4   to do in a comfortable environment.
 5   Q.   And we heard actually Ms. Penelow telling you on this
 6   tape that she felt comfortable airing these kind of concerns
 7   to you.
 8        Was that your impression based on your involvement in
 9   the meeting?
10   A.   Yes.
11   Q.   Okay.
12        And were you working to help strategize about how to
13   make Ms. Penelow feel more comfortable in her position?
14   A.   Yes.
15   Q.   What types of things was Ms. Penelow interested in
16   exploring, if you can remember?
17   A.   I remember she was interested in setting more
18   strategic -- being in more strategic-type projects, so if I
19   remember correctly, her manager and manager's managers were
20   trying to think about how she could think about more business
21   planning-type activities in addition to her sales rep
22   capacity.
23   Q.   At any point, Ms. McGrath, during this meeting that we
24   have the 45-minute tape for, did Ms. Penelow report to you
25   that she believed she was being pressured to promote off
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United States District Court
District of New Jersey

1 label?

2 A.   No.

3 Q.   At any point during this meeting that we have the

4 recording for, did Ms. Penelow report to you that she believed

5 Janssen was bribing physicians?

6 A.   No.

7 Q.   Did Ms. Penelow make any of those types of complaints or

8 concerns about off-label promotion or bribing of doctors going

9 on from her point of view?

10 A.   No.

11 Q.   What would you have done if Ms. Penelow had reported

12 those things to you?

13 A.   If she had, I would have walked down to my manager's

14 office and reported it to her, and then I would have gone to

15 our HCC compliance officer and reported it to her and likely

16 documented both of those instances in an email.

17 Q.   As an HR professional, are you trained and prepared to

18 respond appropriately to a complaint that someone might make

19 as serious as off-label promotion or bribing doctors?

20 A.   I am.

21 Q.   And is that something you would have taken seriously and

22 responded appropriately to?

23 A.   Yes.

24 Q.   Okay.

25   I want to show you some testimony that our jury heard

United States District Court
District of New Jersey

1   from Ms. Penelow about that recording that we just heard.

2   MS. BROWN: Can I have the ELMO, please.

3   BY MS. BROWN:

4   Q.   Ms. Penelow testified in this case, Ms. McGrath. Were

5   you aware of that, ma'am?

6   A.   I'm sorry?

7   Q.   Ms. Penelow testified in the trial.

8   A.   Yes.

9   Q.   Were you aware of that?

10   A.   Yes.

11   Q.   And she told us that she had sworn under oath that in the

12   fall of 2012, she reported off-label activity to HR.

13   And do you see that there in the first question and

14   answer?

15   A.   I do.

16   Q.   And from your point of view working in HR at that time,

17   did that happen?

18   A.   No.

19   Q.   Okay.

20   And then I said to Ms. Penelow: "We asked you at your

21   deposition the very same question, and you swore again that

22   you reported it to HR."

23   And, ma'am, Ms. McGrath, from your point of view in HR,

24   did that take place?

25   A.   No.

United States District Court
District of New Jersey

1 Q.   And then Ms. Penelow of course told us not only did she

2 report it, but she got it on tape, and that's the tape you and

3 I just listened to of that meeting you had with her.

4   Right, ma'am?

5 A.   Correct.

6 Q.   And Ms. Penelow herself told us in this trial that she

7 listened to the tape, and of course it did not contain any

8 evidence that she had reported to you this off-label activity.

9   And then Ms. Penelow testified here that she had to

10 correct that testimony.

11   And that -- from your point of view, ma'am, that

12 testimony would need a correction because it didn't happen.

13   Right?

14 A.   Correct.

15 Q.   Okay.

16   And our jury saw already during Ms. Penelow's testimony

17 how she had originally stated under oath, in her deposition in

18 November of 2012, she decided to go to human resources and

19 report the off-label activity, and we saw how she changed that

20 testimony to delete her original testimony that she had

21 reported the activity.

22   From your point of view, ma'am, nothing was reported --

23 was anything reported to you in November of 2012 from

24 Ms. Penelow about off-label activity?

25 A.   No.

1 Q.   Okay.

2   I then want to talk to you about how -- and then I'll

3 just show you one more, ma'am.

4   In addition to the off-label testimony, our jurors saw

5 a correction Ms. Penelow made to her testimony about off-label

6 content being presented at a speaker program.

7   As you see there, ma'am, she had originally testified

8 that she told human resources about off-label content being

9 presented at a speaker program, and she referenced that

10 meeting with you.

11   Did Ms. Penelow report to you at that meeting any

12 off-label activity going on at a speaker program?

13 A.   No.

14 Q.   All right.

15   And our jury saw that Ms. Penelow did correct that and

16 change that to she did not record the meeting.

17   But what I want to ask you about is the testimony that

18 Ms. Penelow gave when she came into this court before our

19 jury.

20   And let me just ask you this, ma'am: Prior to this

21 meeting with Ms. Penelow in November of 2012, had she ever

22 reported to you as the HR official that there was off-label

23 promotion going on?

24 A.   No.

25 Q.   Prior to this meeting in November of 2012, had she ever

 1 reported to you that there was off-label activity going on at

 2 speaker events?

 3 A.   No.

 4 Q.   Prior to this meeting in 2012, had she ever raised any

 5 similar concerns about alleged compliance allegations

 6 regarding off-label promotion?

 7 A.   No.

 8 Q.   All right.

 9   And I want to show you what Ms. Penelow testified to

10 when she came into this court and ask you some questions about

11 it.

12   This was her counsel's questioning, and it talks about

13 the testimony that she had to correct. And it talks about

14 coming back from medical leave and having a meeting with you

15 in November of 2012.

16   Right? Do you see that there?

17 A.   Yes.

18 Q.   And that meeting did take place. We have the tape.

19   Right?

20 A.   Correct.

21 Q.   There's simply no mention of off-label activity.

22   Correct?

23 A.   Correct.

24 Q.   All right.

25   And Ms. Penelow talks about forgetting what was on the

1 recording and that she wanted to fix her testimony in order to

2 be as truthful as possible.

3   Do you see that, ma'am?

4 A.   I do.

5 Q.   Okay.

6   And what happened later on in her testimony then,

7 ma'am, are two pieces of testimony I want to ask you about.

8   She was asked some questions about the meeting that we

9 listened to with you, and she was asked by her lawyer: "In

10 that meeting, what were you feeling?" The one that we just

11 heard the recording. That's the meeting with you.

12   And she said: "I remember very specifically how I was

13 feeling because it had been almost a year that my accusations

14 had been ignored."

15   Had Ms. Penelow raised with you a year prior to this

16 recording accusations about off-label promotion and speaker

17 bribing?

18 A.   No.

19 Q.   Ms. Penelow said, referring to the meeting with you, "I

20 was very nervous." I think we heard that on the recording.

21   Did you perceive Ms. Penelow to be nervous when she met

22 with you in November of 2012?

23 A.   I didn't think so.

24 Q.   Okay.

25   Did you think she felt -- she appeared to you to be

 1 comfortable to air whatever concerns she had?

 2 A.   I thought she was.

 3 Q.   All right.

 4   Ms. Penelow said: "I told her" -- that's you,

 5 Ms. McGrath -- "I didn't know who to trust, and that's because

 6 I had already told her" -- that's you -- "about what was going

 7 on in the field, and she did nothing about it. So that's why

 8 I decided to tape the recording."

 9   Do you see that, ma'am?

10 A.   I do.

11 Q.   Was there ever a time that Ms. Penelow reported these

12 allegations to you and you ignored it?

13 A.   No.

14 Q.   As an HR professional in your field now for over ten

15 years, is that something you would do if someone came to you

16 with compliance allegations?

17 A.   No.

18 Q.   Ms. Penelow was actually quite specific, Ms. McGrath,

19 about the time period that she believes prior to this tape she

20 reported off-label promotion to you, and I want to show you

21 that testimony and ask you some questions.

22   This is questioning from her lawyer. "Explain to the

23 jury how many times you spoke to Ms. McGrath on the phone.

24   "I went on disability at the beginning of 2012, and

25 that was my first conversation with her, and our conversations

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 1  continued until the end of the year of 2012.  So we had

 2  multiple conversations, possibly up to ten."

 3        Do you see that testimony, ma'am?

 4  A.   Yes.

 5  Q.   Okay.

 6        And then her counsel says:  "So earlier in 2012, or

 7  maybe in 2011, you let us know that you called Ms. McGrath to

 8  explain to her what's happening with Tony Dolisi and what's

 9  happening with the off-label marketing."

10        And her answer was:  "Yes, I told her everything."

11        Ms. McGrath, is that true?

12  A.   No.

13  Q.   How do you know?

14  A.   I wasn't employed with Johnson & Johnson at the end of

15  2011 or early 2012.

16  Q.   Ms. Penelow testified under oath that in early 2012 or

17  maybe even 2011, she reported to you.  And are you telling

18  us you didn't even --

19        MR. RUSS:  Objection, Your Honor.  Can we approach?

20  Mischaracterizes the testimony.

21        THE COURT:  Okay.

22        (Sidebar begins at 3:17 p.m.)

23        MR. RUSS:  Maybe 2011 was part of my question.  She

24  said, I told her in 2012 earlier.  That's not part of her

25  testimony.  I was trying to figure out when she was talking
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 1   about, so Ms. Penelow never said anything happened in 2011.

 2   So to the extent that she --

 3   THE COURT: Hold on. So you are saying it's part of

 4   your question but not the response?

 5   MR. RUSS: Correct.

 6   THE COURT: All right. Show me where she said she

 7   doesn't --

 8   MS. BROWN: She says, "beginning in 2012," in the

 9   first line. That's her testimony, Your Honor.

10   Her --

11   THE COURT: So her answer is 2012.

12   MS. BROWN: Beginning of 2012 in the first question.

13   THE COURT: Right.

14   MS. BROWN: And then in the second question, she says

15   yes to earlier in 2012 or 2011.

16   MR. RUSS: I said maybe in 2011, but she didn't say

17   in 2000- -- I was trying to figure out when she was talking

18   about.

19   THE COURT: Yeah, I get it, but I think this is

20   almost argument. I understand it's in your question, but she

21   says yes. It's been corrected.

22   MS. BROWN: Right.

23   THE COURT: So I'm going to allow that response, and

24   you can cross-examine on it.

25   MR. RUSS: Sure.

United States District Court
District of New Jersey

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 1              THE COURT:  However you want to --

 2              MR. RUSS:  The records have never said -- Ms. Penelow

 3   never says, I reported to her in 2011.

 4              THE COURT:  I know, but if you ask it in the question

 5   and her response is yes, then she adopts that time period in

 6   her response.  No?

 7              MR. RUSS:  Well, I was saying, let -- let us know,

 8   and she didn't clarify.  It's my fault for not asking the

 9   question.

10              THE COURT:  You can focus there on re- -- on

11   cross-examination if you want.  I'm overruling it for now

12   based on that.

13              (Sidebar was concluded at 3:19 p.m.)

14              (Open court.)

15              MS. BROWN:  May I proceed, Your Honor?

16              THE COURT:  You may.

17   BY MS. BROWN:

18   Q.   So let me just ask you a couple of things, then.

19        Ms. Penelow responded that Yes, earlier in 2012 or

20   maybe 2011 she had made these reports to you.

21        First of all, during the entire time period that you

22   worked in a position with Ms. Penelow, did she ever report to

23   you off-label marketing or off-label promotion?

24   A.   No.

25   Q.   Were you even working at Janssen in 2011?
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 1  A.    Not at Janssen.

 2  Q.    Where were you, ma'am?

 3  A.    I was in grad school in Pittsburgh.

 4  Q.    Okay.

 5        What about early 2012?  Were you working at Janssen?

 6  A.    No.  I was still in grad school.

 7  Q.    Okay.

 8        Up here a second time in Ms. Penelow's testimony here

 9  in the court:  "Explain to the jury how many times you spoke

10  to her beginning of 2012."

11        Ma'am, in the beginning of 2012, were you working for

12  Janssen?

13  A.    No.

14  Q.    Okay.

15        Is it true that you had some additional phone

16  conversations with Ms. Penelow?

17  A.    We did.

18  Q.    Did they ever involve the topic of her reporting to you

19  off-label marketing or off-label promotion?

20  A.    No.

21  Q.    Thanks very much, Ms. McGrath.  I have no further

22  questions for you.  Thanks.

23  A.    Thanks.

24        THE COURT:  All right.  Thank you, Ms. Brown.

25        Mr. Russ?
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United States District Court
District of New Jersey

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 1              MR. RUSS:  Thank you, Your Honor.

 2       (CROSS-EXAMINATION BY MR. RUSS:)

 3    Q.   Good afternoon, Ms. McGrath.

 4    A.   Good afternoon.

 5    Q.   My name is Josh Russ.  I represent Jessica Penelow and

 6    Christine Brancaccio.

 7            You and I have never met?

 8    A.   Correct.

 9    Q.   Okay.

10            Have you had an opportunity before today to meet

11    with -- are you represented today?

12    A.   By J&J.

13    Q.   J&J's counsel also represent you?

14    A.   Correct.

15    Q.   Have you had a chance to meet with them before your

16    testimony?

17    A.   Correct.

18    Q.   Did you listen to the audio tape that we just heard

19    played in open court?

20    A.   Not before today.

21    Q.   You've never -- you heard it today?

22    A.   I heard it today.

23    Q.   In court or before?

24    A.   Never before.  Just today.

25    Q.   Okay.
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United States District Court
District of New Jersey

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 1          So you haven't listened to the whole thing?

 2   A.   No.

 3   Q.   Okay.

 4          You -- you had just started at J&J in the summer of

 5   2012.

 6          Is that right?

 7   A.   For the full-time role, yes.

 8   Q.   So it was right out of grad school?

 9   A.   Correct.

10   Q.   But you had previously been an intern at J&J in 2011.

11          Correct?

12   A.   Correct.

13   Q.   Okay.

14          You met Ms. Penelow pretty early on in your employment

15   with J&J.

16          Is that fair?

17   A.   Correct.

18   Q.   You liked her?

19   A.   Yep.

20   Q.   You thought she was honest.

21          Correct?

22   A.   Correct.

23   Q.   You didn't have any reason to distrust her?

24   A.   Correct.

25   Q.   But you also knew she was going through a pretty rough
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United States District Court
District of New Jersey

1 time.

2   Fair?

3 A.   I knew she was on disability.

4 Q.   Actually, she told you she had a hostile work

5 environment, didn't she?

6 A.   She told me she was having trouble with her manager.

7 Q.   Specifically, she told you she was dealing with a hostile

8 work environment?

9 A.   So when employees tell me that, I listen to both sides,

10 so I had a conversation with her, and I had a conversation

11 with her manager as well after.

12 Q.   So she told you she had a hostile work environment?

13 A.   Those are her words.

14 Q.   Right.

15   And Ms. Penelow remembers having approximately ten or

16 so calls in that one year with you.

17   Do you have any reason to dispute that you had ten or

18 so phone calls with Ms. Penelow?

19 A.   Over the course of the year I was employed, I don't know

20 if it was ten, but between email and phone calls, probably ten

21 interactions.

22 Q.   Okay.

23   Now, she did say in response to a question that I

24 posed, which is -- you just saw up there -- my fault, not a

25 very good question. I said: "Earlier in 2012 or 2011, you

United States District Court
District of New Jersey

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 1  let us know, Ms. Penelow."

 2         She said in earlier 2012, she had been in touch with

 3  you before the meeting that we just heard the audio from.

 4         Do you understand that?

 5  A.   I do.

 6  Q.   Okay.

 7         And, in fact, she had -- you had had several hours of

 8  conversations with her.

 9         Fair?

10  A.   Before we met in person?

11  Q.   Yes, ma'am.

12  A.   No.

13  Q.   No?

14  A.   Not that I recall.

15  Q.   Not that you recall because it was 12 years ago,

16  Ms. McGrath, wasn't it?  It was 12 years ago that you had

17  these conversations with Ms. Penelow, wasn't it?

18  A.   Correct.

19  Q.   And you had just started in your employment right out of

20  business school with J&J.

21         Correct?

22  A.   Correct.

23  Q.   Your first pharmaceutical position?

24  A.   Correct.

25  Q.   Do you remember Ms. Penelow talking to you about MIRs?
```

1   A.   No.

2   Q.   Do you remember Ms. Penelow talking to you about her

3   sales?

4   A.   No.

5   Q.   Her doctors that she was calling on?

6   A.   No.

7   Q.   Her numbers?

8   A.   No.

9   Q.   You don't remember any of that -- and we can listen to

10   the whole conversation that was recorded.

11   You don't remember her telling you Tony Dolisi was

12   getting onto her about her sales?

13   A.   I remember difficulty she and Tony were having in

14   communication overall.

15   Q.   But to be fair -- and you said, I think, with Ms. Brown

16   that you, over the last 12 years, have moved up through the

17   ranks of J&J with more and more responsibility.

18   Right?

19   A.   Correct.

20   Q.   How many people do you think over the last 12 years that

21   you have overseen in your position as a human resource

22   professional?

23   A.   Meaning directly reported to me or that I've supported as

24   an employee?

25   Q.   Let's start with directly reported.

1   A.   Probably ten over the course of my period of time at J&J.

2   Q.   How about how many employees that you're responsible for?

3   A.   Hundreds.

4   Q.   And in that position, Ms. McGrath, and in the various

5   positions since your time at Tibotec, you've had a lot of

6   calls and a lot of meetings with employees.

7   Fair?

8   A.   I have.

9   Q.   All right.

10   Standard stuff that HR deals with with employee

11   complaints.

12   Correct?

13   A.   Correct.

14   Q.   Okay.

15   Now, you said you don't remember having hours of

16   conversations with Ms. Penelow before that November call or

17   that November meeting.

18   Is that fair?

19   A.   Correct.

20   Q.   And it's not a memory test. It's not a memory test.

21   It's okay if you don't recall every conversation you had

22   12 years ago.

23   Do you understand?

24   A.   Yes.

25   Q.   Do you understand that also Ms. Penelow in November of

```
 1   2012 was about to file this lawsuit.

 2        Did you know that?

 3   A.   I did not.

 4   Q.   Ms. Penelow was dealing with a new lawsuit that she was

 5   about to file in a hostile work environment, and she was very

 6   attuned to the conversation she was having at Janssen.

 7        Did you know that?

 8   A.   I did not.

 9   Q.   Did you know that she had previously reported her

10   concerns to Anthony Dolisi --

11   A.   I did not.

12   Q.   -- about off-label marketing?

13        Did you know that?

14   A.   I did not.

15   Q.   You don't have any reason to dispute that?

16   A.   I didn't know.

17   Q.   So Ms. Brown just showed you the testimony where she said

18   that "my concerns have been ignored for over a year."

19        Did you know she was -- that she reported to her

20   management, not HR, for years?

21   A.   No.

22   Q.   And you have no reason to dispute that?

23   A.   Correct.

24   Q.   Do you know who -- did you talk to Tony Dolisi about

25   anything related to off-label marketing?
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United States District Court
District of New Jersey

1 A.   No.

2 Q.   Do you know who Frank Murphy is?

3 A.   I do.

4 Q.   Do you know who Nancy Peterson is?

5 A.   Her name is familiar.

6 Q.   Do you know who Joanne Cesario is?

7 A.   I don't recall meeting her. Her name maybe came up once.

8 Q.   You don't recall Joanne Cesario making concerns --

9 concerns known about off-label marketing to HR in 2012 when

10 you were there?

11 A.   Not to me.

12 Q.   How big was your HR department?

13 A.   Across -- for Janssen Therapeutics?

14 Q.   Yes, ma'am.

15 A.   There were two of us.

16 Q.   So it was you and Delores Smith?

17 A.   No.

18 Q.   Where was Delores Smith?

19 A.   She was in a different role at J&J when I joined.

20 Q.   But she wasn't HR in 2012.

21   Fair?

22 A.   In HR, correct.

23 Q.   Okay.

24   So you don't remember the name Joanne Cesario?

25 A.   Her name came up once, maybe, but I never had

United States District Court
District of New Jersey

 1   interactions with her. We had to remove her name from our

 2   year-end compensation calibration grid because she had already

 3   left the company.

 4   Q.   You don't recall any concerns she raised about off-label

 5   marketing.

 6   A.   No.

 7   Q.   That's fair?

 8   A.   Correct.

 9   MR. RUSS: Let's take a look -- listen, Ms. Johnson,

10   to Defense Exhibit 6029-A, clip 1.4.

11   BY MR. RUSS:

12   Q.   This is a clip from the same audio recording that we just

13   heard with Ms. Brown.

14   Okay?

15   A.   Okay.

16   (Audio recording played at this time.)

17   BY MR. RUSS:

18   Q.   Did you hear your voice on that recording, Ms. McGrath?

19   A.   I did.

20   Q.   Did you hear yourself, and it maybe refreshes your

21   recollection, that you had been meeting for two weeks for

22   several hours with Ms. Penelow before the in-person meeting?

23   A.   We did not. That was an hour-long meeting in and of

24   itself. But we did not -- we maybe spoke on the phone once or

25   twice, and it was to help with coordinating meeting up in my

 1 office that time in Titusville.

 2 Q.   Did you hear yourself on that recording say "multiple

 3 weeks for several hours"?

 4 A.   I did. We didn't meet for multiple weeks. We emailed,

 5 but there were no multiple hours of conversations.

 6 Q.   But you did say "several hours."

 7 A.   I did.

 8 Q.   Okay.

 9   Did you bring any notes with you from any of those

10 phone calls?

11 A.   No.

12 Q.   Did you keep notes of phone calls that you had with

13 Ms. Penelow?

14 A.   No.

15 Q.   In fact, you didn't keep files, did you?

16 A.   I have email records, but I showed Jessica there was no

17 HR filing cabinet in my office.

18 Q.   You don't remember opening your drawer during that

19 meeting and saying, "I don't have any files on anybody"?

20 A.   And the intent of that was to make her comfortable. We

21 have a separate HR filing resource. It's not in my office.

22 Q.   So you didn't keep any notes of the prior conversations

23 that you had with Ms. Penelow via phone.

24   Fair?

25 A.   Correct. I sent her -- I know there were follow-up

 1   emails between the two of us, thanking her for connecting.

 2   Q.   Maybe we can see some of those follow-up emails, but you

 3   didn't bring any notes -- or you don't have any notes, that

 4   you know about, about your phone calls and Ms. Penelow leading

 5   up to that meeting.

 6   A.   No.

 7   Q.   Okay.

 8   Now, Ms. McGrath, you're not -- just like it's not a

 9   memory test for you, you're not saying that Ms. Penelow might

10   have a different memory than you do about the conversations

11   she had with you, right, after you started at J&J.

12   Fair?

13   A.   Fair.

14   Q.   And memories differ.

15   Right?

16   A.   Sure.

17   Q.   She might have remembered telling you something about

18   what she was dealing with with Mr. Dolisi that she thought you

19   understood that maybe didn't get through.

20   Right?

21   A.   Perhaps.

22   Q.   You're not accusing her of lying, are you?

23   A.   No. I'm just saying what happened.

24   Q.   You're not accusing her of lying to you about that

25   conversation.

1 A.   I can only speak from my experience, and she never

2 reported any off-label marketing to me.

3 Q.   Okay.

4   And you don't have any notes of the prior conversation.

5   Right?

6 A.   No. Just the follow-up thanking her for connecting and

7 making sure she knew how to get to my office.

8 Q.   You can't dispute her number, that she thought she talked

9 to you ten times, before that meeting?

10 A.   I mean, my Outlook calendar would likely dispute it. I

11 have records of phone calls from meetings that I would have

12 had. I would have sent out a meeting invite, and none of that

13 exists.

14 Q.   You're speculating. You said, "likely would dispute

15 that."

16   Did you look at your Outlook calendar?

17 A.   No.

18 Q.   So you're saying, "would likely dispute it," but you have

19 not looked --

20 A.   No. My Outlook calendar, yes. I did look at my Outlook

21 calendar, and there was at least one phone call we had set up

22 prior to us meeting in November.

23 Q.   Okay.

24   But you had also had several hours of conversation, at

25 least according to you, back in 2012.

1   Fair?

2   A.   That hour of conversation, correct.

3   Q.   Several hours, according to you.

4   Fair?

5   A.   Fair.

6   Q.   Okay.

7   Now, you understand, Ms. McGrath, this is not an

8   employment case that we are here that you're testifying in?

9   A.   Correct.

10   Q.   Okay.

11   You understand that whether or not Jessica Penelow

12   reported to anybody at Janssen about what she saw and what she

13   witnessed doesn't change what actually happened on the ground.

14   Do you understand that?

15   A.   I do.

16   Q.   And you're not saying that the off-label marketing didn't

17   occur because that wasn't your job.

18   A.   I was not aware of any.

19   Q.   You didn't go to speaker programs?

20   A.   Correct.

21   Q.   And you understand that it's not a requirement for

22   Ms. Penelow to report to anybody, even though she did, in

23   order to file a False Claims Act suit with the government.

24   Do you understand that?

25   A.   I do.

United States District Court
District of New Jersey

1   Q.   Do you understand that Ms. Penelow thought that the

2   conversation she had with you in your office that she recorded

3   was the conversation that she had had with you where she

4   believed she reported misconduct at Janssen.

5   You understand that's what she thought in her

6   deposition.

7   A.   If you're saying that's true.

8   Q.   Well, Ms. Brown just showed you where she changed her

9   testimony and said, "I was mistaken. It wasn't that way. I'm

10 fixing it."

11   Right? She showed you that on the ELMO?

12 A.   Correct. Yep.

13 Q.   Are you a hundred percent certain with all the calls that

14 you had with Ms. Penelow that you never discussed her sales

15 metrics?

16 A.   I don't recall discussing sales metrics at all.

17 Q.   Or medical information requests?

18 A.   We had -- that was all managed through a third-party

19 provider.

20 Q.   You don't recall having discussions with her about --

21 well, you said hostile work environment?

22 A.   So we talked about challenges she had with her manager,

23 yes.

24 Q.   And she -- Ms. Brown just asked you, Did she seem like

25 she was comfortable in that conversation with you, and you

 1 said you thought so?

 2 A.   I thought she was comfortable.

 3 Q.   She was afraid, wasn't she?

 4 A.   I don't think she was afraid of me, if that's what you're

 5 asking.

 6 Q.   She was afraid about her situation that was going on at

 7 Janssen, wasn't she?

 8 A.   Employees come to me to talk about their concerns, and I

 9 listen and try to help them.

10 Q.   So that's not my question, Ms. McGrath.

11   My client, Ms. Penelow, was afraid of what was going on

12 at Janssen, and she told you that, didn't she?

13 A.   She told me she was having trouble with her manager.

14 Q.   Let's take a look at clip -- or listen to clip 1.6.

15   (Audio recording played at this time.)

16 BY MR. RUSS:

17 Q.   You don't remember that either, do you, that she was

18 "scared as hell"?

19 A.   I remember she was very -- she felt comfortable to tell

20 me about all of these things, and I could imagine that would

21 be difficult for her to do. So if she felt a certain way...

22 Q.   She told you she was "scared as hell," didn't she?

23 A.   If that was her words.

24 Q.   If that was? Ms. McGrath, do you want to listen to it

25 again?

United States District Court
District of New Jersey

1   A.   No.   That's fine.   I'm sorry.

2   Q.   She said, "I'm scared as hell," didn't she?

3   A.   She did.

4   Q.   And she -- when she was telling you she was scared as

5   hell, she was talking about Tony Dolisi, wasn't she?

6   A.   Concerns with Tony, her manager, correct.

7   MR. RUSS: No further questions, Your Honor.

8   THE COURT: All right, thank you.

9   Ms. Brown, any redirect?

10   MS. BROWN: Briefly, Your Honor.

11   THE COURT: Okay.

12 (REDIRECT EXAMINATION BY MS. BROWN:)

13 Q.   Ms. McGrath, did you believe Ms. Penelow was comfortable

14 talking to you?

15 A.   I did.

16   MS. BROWN: Can we play video clip number 5, please.

17   (Video clip played at this time.)

18 BY MS. BROWN:

19 Q.   Ms. McGrath, did Ms. Penelow say at the beginning of that

20 she felt comfortable with you?

21 A.   She did.

22 Q.   Is that consistent with your recollection?

23 A.   Yes.

24 Q.   And, Ms. McGrath --

25   MS. BROWN: If I could have the ELMO, please.

United States District Court
District of New Jersey

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 1   BY MS. BROWN:

 2   Q.   We can only ask you to remember what happened from your

 3   point of view.

 4        Okay, ma'am?

 5   A.   Correct.

 6   Q.   Do you believe, from your point of view, that Ms. Penelow

 7   ever reported to you off-label promotion?

 8   A.   No.

 9   Q.   Is that something you believe you would remember, even

10   ten years later?

11   A.   Correct.

12   Q.   Is that something that you believe in your role as an HR

13   professional you would have documented?

14   A.   Yes.

15   Q.   And is that something that is a physical impossibility

16   based on the time period that you worked at this company?

17   A.   Correct.

18   Q.   Is it physically impossible that any conversation between

19   you and Ms. Penelow took place in the beginning of 2012?

20   A.   Correct.

21   Q.   Is it physically possible?

22   A.   Oh, no, it's not physically possible.

23   Q.   Because you weren't working at the company?

24   A.   Correct.

25   Q.   And when Ms. Penelow swore under oath that she told you
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United States District Court
District of New Jersey

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 1  everything in earlier 2012 or maybe 2011, were you working at

 2  the company during either of those time periods?

 3  A.   No.

 4  Q.   Is there any doubt in your mind, Ms. McGrath, that the

 5  testimony Ms. Penelow gave to our jury that she reported to

 6  you off-label marketing is not accurate?

 7  A.   Correct.

 8          MS. BROWN:  No further questions.  Thank you.

 9          THE COURT:  All right, thank you, Ms. Brown.

10        Ms. McGrath, you're excused from the trial.  Thank you.

11          THE WITNESS:  Thank you.

12          THE COURT:  Ms. Brown, what do we have next?

13          MS. BROWN:  We are going to call Ms. Kim Saladana,

14  Your Honor.

15        May we get her?

16          THE COURT:  Yes.

17          MS. BROWN:  Thank you.

18        Your Honor, may we call Ms. Kim Saladana?

19          MR. KLEIN:  Janssen calls Kim Saladana.

20          THE COURT:  Yep, you've got it.

21        Kim, you want to swear her in.

22        No, no.  Come on up.  She's going to swear you in

23  either when you get in the box or before, wherever it's

24  convenient.

25  (**KIMBERLY SALADANA**, HAVING BEEN DULY SWORN/AFFIRMED, TESTIFIED
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 1  AS FOLLOWS:)

 2         THE DEPUTY COURT CLERK:  Please state your name and

 3  the spelling of your last name for the record.

 4         THE WITNESS:  Kimberly Saladana, S-A-L-A-D-A-N-A.

 5  (DIRECT EXAMINATION BY MR. KLEIN:)

 6  Q.   Good afternoon, Ms. Saladana.  Welcome.

 7  A.   Thank you.

 8  Q.   I have a few questions for you this afternoon, but before

 9  we get into that, can you tell the jury a little bit about

10  yourself, sort of where you grew up, where you went to school?

11  A.   Sure.

12         My name is Kim Saladana.  I'm Canadian.  I grew up in

13  Victoria, British Columbia, Canada.  I went to school at the

14  University of Victoria and then to Royal Roads University.

15         Got a French degree.  Wasn't terribly helpful.  Got a

16  business degree.  Then got my first pharmaceutical job in

17  Canada as a sales rep, and that was on the West Coast.

18         I did okay.  I got a better sales -- I got a role in --

19  a special role in HIV, did that for a couple of years.

20         Was then offered a job in marketing and moved to

21  Toronto, which is across the country.  Did a marketing job in

22  Toronto for a couple of years, and then I was at a conference

23  and --

24  Q.   Ms. Saladana --

25  A.   Oh, sorry.
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United States District Court
District of New Jersey

1 Q.   Hold on. Maybe we can --

2 A.   You bet. Sorry.

3 Q.   -- take it one step at a time.

4   So what was your first job in health care?

5 A.   I worked for Abbott Laboratories, and I was a generalist

6 rep. So I had a proton-pump inhibitor and an antibiotic.

7 Q.   When was that?

8 A.   1998 to 2000.

9 Q.   1998. Okay.

10   And then what was the -- your next position after that?

11 A.   Same company, got an HIV role and launched a drug called

12 Kaletra.

13 Q.   Okay.

14   And I think the jury's heard a bit about Kaletra during

15 the proceedings here.

16   What was your next position after the Kaletra role?

17 A.   I took a job in Toronto with Roche Pharmaceuticals, and I

18 was in a marketing role -- I was the marketing team -- and

19 launched a drug called Fuzeon.

20 Q.   Okay.

21   Was that also in the HIV space?

22 A.   It was, yeah. It was the first injectable for HIV.

23 Q.   Got it. Okay.

24   And then after Roche?

25 A.   Then I went home to the West Coast for about a year. And

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 1   I had remembered hearing about this company, Tibotec, that had

 2   these unbelievable drugs in development.  Via prior to

 3   conference, I was having coffee with one of the infectious

 4   disease specialists who worked in Ottawa.  And one of my old

 5   HIV customers, Brian Woodfall, was working with Tibotec.  He

 6   was living in Belgium, and I reached out to him and asked him,

 7   What do you think about the company?  What do you think of

 8   these drugs, and, you know, I would be interested in

 9   opportunities.

10          And he put me in touch with a woman named Gail

11   Sikorski, who was vice president of this tiny, little biotech

12   company called Tibotec.

13   Q.   Okay.

14          And at that time -- you said it was a tiny, little

15   biotech company.

16          About how many employees did it have?

17   A.   Oh, geez.  When I started, 20.

18   Q.   20.

19          And this was what year?

20   A.   June 2005.

21   Q.   2005.  Okay.

22          And what was your position at Tibotec at that time?

23   A.   I was brought on as a product manager.

24   Q.   A product manager.

25          And what were your responsibilities in that role?
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United States District Court
District of New Jersey

1   A.   It was a year before we would ever potentially have a

2   drug on the market or approved, so it was all of the things

3   one does in getting ready to launch a product.

4   So we were doing market research, we were looking at

5   the HIV health care space, who were the providers caring for

6   people living with HIV.

7   For me, we were doing market research, that kind of

8   thing.

9   Q.   Okay.

10   And did there come a point where you became involved

11   with Tibotec's speaker bureau program?

12   A.   Yeah.   I became the manager or the lead for that.

13   Q.   Okay.

14   And we'll talk about that in a little more detail, but

15   I just wanted to ask you, what initially drew you to the HIV

16   space?

17   A.   HIV at the time was just -- treatment options were

18   horrible.   They're really, really tough and very limited.   It

19   was difficult for patients to be able to take the regimens.

20   They had lots of different drugs, high pill burdens, take it

21   with food, without food, a high fat meal, drink lots of water

22   when you take this one because you'll get kidney stones.   It

23   was -- it was really challenging.

24   And people would take sequential -- we called them back

25   then -- cocktails, but sequential regimens and fail.   And then

1 there was, you know, whatever was available next for them to

2 take.

3 Q.   Right.

4   Is it fair to say you hoped you were -- thought it

5 would be an opportunity to make a difference?

6 A.   Oh, absolutely. I think -- I mean, I certainly felt like

7 I was doing good and valued and worthwhile work. And the

8 folks I worked with, we all worked really, really hard and

9 were dedicated to that therapeutic area, for sure.

10 Q.   Okay.

11   You said you were in that role from 2005 until roughly

12 when? I just want to get the chronology right. I mean --

13 A.   Yep.

14   Started as an employee in June 2005, and I left the job

15 as an employee on a Friday, mid-March 2007 and started as a

16 contractor on the Monday.

17 Q.   Okay.

18   And did your role change, or was it more of a --

19 A.   No. I was doing absolutely exactly the same thing. My

20 email went from a TTU.S to a non-TTU.S ending.

21 Q.   And then did you have another role after that, or were

22 you a contractor for the remainder?

23 A.   I contracted for two years, and then tax laws being what

24 they are, you have to not be a contractor anymore.

25   So then I worked as a freelancer basically. I started

 1   my own little company and worked on medical --

 2   Q.   When was that, roughly?

 3   A.   2007 -- or 2009.

 4   Q.   2009.

 5   So you worked at Tibotec as an employee or contractor

 6   from '05 to '09?

 7   A.   Correct.

 8   Q.   All right.

 9   And you said you were responsible for the speaker

10   program for -- for Prezista or for Intelence or for another

11   medicine?

12   A.   For Prezista.

13   Q.   For Prezista. Okay.

14   All right. Very good.

15   So let's talk a little bit about that. So what -- you

16   know, the jury's heard quite a bit about speaker bureau,

17   speaker programs, but let's just start from the beginning.

18   What was the speaker bureau that you were to set up at

19   Tibotec starting in 2005?

20   A.   Okay. Well, in HIV there are -- it's actually a fairly

21   small therapeutic area. There's only around 5,000 providers

22   who care for people living with HIV.

23   So our -- at Tibotec, Janssen, our speaker bureau was

24   relatively small. We were looking to set up a speaker bureau,

25   and that's where you get an X number of people, physicians

1 typically, to -- you train them, and they go out and speak

2 promotionally, educate other health care providers about

3 this -- your new product.

4 Q.   Okay.

5   I'm going to show you a document here.

6   MR. KLEIN: Mr. Morales, if we could bring up D-4006,

7 just for the witness and counsel, please.

8 BY MR. KLEIN:

9 Q.   All right.

10   So Ms. Saladana, do you recognize this document?

11 A.   Yeah. It is the -- it's the policy document, basically

12 the rule book on how to set up a Promotional Speaker Bureau.

13 Q.   Okay.

14   MR. KLEIN: Your Honor, we move to admit D-4006.

15   MR. WIRMANI: No objection.

16   THE COURT: So admitted.

17 (Defendants' Exhibit D-4006 in evidence.)

18   MR. KLEIN: Can we publish that to the jury, please.

19 All right.

20 BY MR. KLEIN:

21 Q.   So, Ms. Saladana, you said this is the policy that

22 governs the Promotional Speaker Bureau for Prezista at Tibotec

23 in 2005.

24   Correct?

25 A.   Yes.

United States District Court
District of New Jersey

1 Q.   Okay.

2   So would this have been the policy that governed the

3 first iteration of the speaker program that coincided with the

4 launch of Prezista in 2006?

5 A.   Absolutely.

6 Q.   Okay.

7   And based on your understanding, during your time at

8 the company, were the policy -- was the policy or the policies

9 that governed the Prezista speaker program, you know,

10 substantively the same?

11 A.   Yes.

12 Q.   Okay.

13   MR. KLEIN: So, Mr. Morales, if we could go to page 2

14 of the document.

15   Sorry. Page 3.

16 BY MR. KLEIN:

17 Q.   You'll see there are various provisions about how the

18 speaker program can be run. And you see under that first

19 bullet labeled "Promotion."

20   Do you see that?

21 A.   I do.

22 Q.   All right.

23   It says, "Information presented by speakers must be

24 within approved product labeling containing fair balance with

25 regard to the safety and efficacy of the company products and

 1 | be approved through the company copy review process."

 2 | Do you see that?

 3 | A.   I do.

 4 | Q.   Okay.

 5 | So can you tell us a little bit about what that means

 6 | in practice. So the information presented by the speakers has

 7 | to be approved through the company copy review process.

 8 | What does that mean, practically?

 9 | A.   Okay. So you would create a slide deck based on the

10 | FDA-approved package insert that contains all of the

11 | information about the product.

12 | So we would build a slide deck, and the Promotional

13 | Review Committee was a multidisciplinary group of people who

14 | would sit in a room for hours on end, every week, and parse

15 | out every single word of that slide deck. So it can -- the

16 | committee was marketing, legal, health care compliance,

17 | clinical -- I don't think I'm missing anyone.

18 | And so we would review, we would review every sentence,

19 | every word of that slide deck and to ensure that it

20 | represented the clinical information contained within the

21 | package insert appropriately.

22 | Q.   Okay.

23 | And those -- just to be clear, those were the materials

24 | for the speakers to use --

25 | A.   Yeah.

1   Q.   -- when they spoke at these events?

2   A.   So that slide deck would get approved. It would be

3   submitted to FDA for them to have a look at and approve.

4   Q.   Okay.

5   A.   And then it would be provided to speakers once they were

6   trained. So they would be trained on that first.

7   Q.   Okay.

8   And when you say it was submitted to FDA, is that

9   through DDMAC or -- which the jury has heard a little bit

10   about -- or another part of FDA? Do you know?

11   A.   DDMAC at the time.

12   Q.   DDMAC. Okay.

13   And so to your knowledge during the time you're at the

14   company, were all the speaker materials submitted to DDMAC for

15   their review?

16   A.   Anything that would be customer facing went to DDMAC.

17   So, yes.

18   Q.   Okay.

19   And do you remember whether DDMAC had any comments or

20   feedback on any of the materials?

21   A.   Sometimes they would come back, but -- and we would

22   adjust the materials based on their comments, of course.

23   Q.   Okay.

24   So is it fair to say -- or I guess, you know, was it

25   your understanding that the -- the materials the speakers

United States District Court
District of New Jersey

 1 ultimately ended up presenting had been vetted by DDMAC and

 2 incorporated any comments that they had?

 3 A.   Absolutely.

 4 Q.   All right.

 5   You see the -- the second bullet there, "Speakers may

 6 only use slides that have been approved by the company copy

 7 review process. Speakers may not add their own slides."

 8   So based on your understanding, was the speaker bureau

 9 implementing consistent with that policy directive?

10 A.   Absolutely -- yes, absolutely.

11 Q.   Okay.

12   What would happen if it came to your attention that a

13 speaker was using slides that had not been approved by the

14 company?

15 A.   Well, if any J&J employee was at a program and they

16 witnessed this happen, they had a duty to report that

17 infraction, and there were several mechanisms to do so.

18   And then we would address that directly with the

19 speaker, and when I say "we," it wouldn't be someone in

20 marketing. It would be someone in health care compliance that

21 would speak with them, reinforce what they were contractually

22 obligated to do.

23   They would be retrained in some cases or removed.

24   MR. KLEIN: Mr. Morales, if we could bring up just

25 for the witness and counsel Defendants' Exhibit 4019.

United States District Court
District of New Jersey

1   BY MR. KLEIN:

2   Q.   Ms. Saladana, do you see this document?

3   A.   Yes.

4   Q.   It's an email from you to -- it looks like it was a

5   couple of LISTSERVS, OBI 44, OBI 45, OBI 47, 48.

6   Do you know what those represent?

7   A.   Districts within the -- so sales reps and sales managers

8   nationally.

9   Q.   Nationally.

10   So this is an email from you on July 24th, 2006 to the

11 national sales team effectively.

12   Is that accurate?

13 A.   Correct.

14 Q.   Okay.

15   MR. KLEIN: Your Honor, we'd move to admit D-4019.

16   MR. WIRMANI: No objection.

17   THE COURT: So admitted.

18   (Defendants' Exhibit 4019 in evidence.)

19   MR. KLEIN: All right.

20 BY MR. KLEIN:

21 Q.   Ms. Saladana, you can see, in the email, you write: Dear

22 Prezista team, we've been receiving many inquiries surrounding

23 the same theme and thought a clear communication was in

24 order."

25   And you'll see "The question relates to the speaker

United States District Court
District of New Jersey

 1 bureau and a speaker's ability to use backup slides to address

 2 unsolicited off-label questions."

 3   Do you see that?

 4 A.   I do.

 5 Q.   All right.

 6   And then what was your response to this situation?

 7 A.   Sorry. I'm not -- I'm not sure exactly what your

 8 question is.

 9 Q.   So based on this email -- do you see further down in the

10 email --

11 A.   Uh-huh.

12 Q.   -- where it says, "HCC guidance indicates that a speaker

13 cannot use those slides" --

14 A.   Yes.

15 Q.   -- bottom paragraph -- "to address the off-label

16 questions. Further, Tibotec Therapeutics is not able to

17 furnish speakers with backup slide decks to address off-label

18 questions."

19 A.   Right.

20 Q.   And then it attaches a slide, a training slide related to

21 that.

22   Do you see that?

23 A.   Yes.

24 Q.   Okay.

25   So was this consistent with the policy provision that

 1   we just looked at regarding use of only -- speakers only being

 2   able to use company-approved slides?

 3   A.   Yes, absolutely. So the speakers were allowed to use the

 4   promotional slide deck which had been reviewed and approved

 5   and provided to them and only that slide deck.

 6   Q.   Okay.

 7   Were you ever -- at the time at the company, did you

 8   become aware of incidents where folks would use unapproved

 9   slides at speaker programs?

10   A.   I did become aware, not very often, but I did become

11   aware through either emails -- or emails generally was how we

12   conducted -- or information was exchanged.

13   But, yes, I did become aware from time to time that

14   speakers took the liberty of using their own slides.

15   Q.   Okay.

16   And then what would happen? How would the company

17   address that situation?

18   A.   It would get reported to HC- -- health care compliance

19   and health care -- someone in health care compliance would

20   then meet with that speaker.

21   Q.   Okay.

22   Were you ever aware of speakers being disciplined or

23   removed from the speaker bureau for -- for that kind of an

24   infraction?

25   A.   I don't recall anyone being removed. They may not have

United States District Court
District of New Jersey

 1 ever been used again.

 2 Q.   Okay.

 3   You will see --

 4   MR. KLEIN: If we could go back, Mr. Morales, to

 5 D-4006. Go back to the policy document for a minute.

 6 BY MR. KLEIN:

 7 Q.   Still on page 3, so the fourth bullet down, the fourth

 8 sub-bullet says, "Speakers at the company must stay on label.

 9 If, during the course of the program, the speaker is asked an

10 off-label question by an invited health care provider, the

11 speaker may answer the question.

12   "When answering an unsolicited off-label question, the

13 speaker must communicate to the audience the information being

14 discussed is not within the approved labeling for the

15 product."

16   So essentially it looks this is a prohibition against

17 speakers speaking off label.

18   Is that correct?

19 A.   Yes. They were trained to present the approved slide

20 deck and only the approved slide deck. If someone in

21 attendance had a question, they were permitted to answer that

22 question and clearly state it was based on their own opinion

23 or experience.

24 Q.   And same thing: If it came to your attention that a

25 speaker had spoken off label at a speaking event, what would

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 1   happen?

 2   A.   As long as they addressed the question --

 3   Q.   Uh-huh.

 4   A.   -- stated that it was based on their experience and went

 5   right back to the approved presentation, that was permitted.

 6   Q.   Okay.

 7        Let's look at D-4123, please.

 8           THE COURT:  Mr. Klein, before we get into the new

 9   document --

10           MR. KLEIN:  Yes.

11           THE COURT:  -- I want to give one more ten-minute

12   break before we get to the final one-hour stretch.  Can we do

13   it now?

14           MR. KLEIN:  Absolutely, Your Honor.

15           THE COURT:  All right.  Then let's do.  Let's do our

16   last short break, folks.  Then we're going to go to 5.

17           MR. KLEIN:  Thank you.

18           THE DEPUTY COURT CLERK:  All rise.

19           (A short recess occurred.)

20           THE DEPUTY COURT CLERK:  Please remain seated.

21           THE COURT:  Mr. Klein, we ready to go?

22           MR. KLEIN:  We are.

23           THE COURT:  All right.

24           THE DEPUTY COURT CLERK:  All rise.

25        (Jury enters the courtroom.)
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United States District Court
District of New Jersey

1   THE COURT: All right, folks. Everybody have a seat.

2   Mr. Klein, whenever you're ready you may proceed.

3   And, Ms. Saladana, just as a reminder, you are still

4 under oath from earlier. All right?

5   MR. KLEIN: All right. Thank you, Your Honor.

6 BY MR. KLEIN:

7 Q.   Ms. Saladana, before the break, we were talking about the

8 policy prohibition against speakers speaking off label. Do

9 you remember that?

10 A.   I do.

11 Q.   Okay.

12   MR. KLEIN: Mr. Morales, can we pull up just for the

13 witness and counsel Defendants' Exhibit 4123.

14 BY MR. KLEIN:

15 Q.   All right.

16   Ms. Saladana, do you see the document on the screen in

17 front of you there?

18 A.   I do, yes.

19 Q.   And it's an email that you wrote to several folks in the

20 sales group on September 8th, 2006.

21   Do you see that?

22 A.   I do, yeah.

23 Q.   All right.

24   And it relates to a Dr. Brian Marsh.

25   Do you see that?

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 1  A.   Yes, I do.

 2  Q.   Okay.

 3       MR. KLEIN:  Your Honor, we'd move to admit

 4  Defendants' Exhibit 4123.

 5       MR. WIRMANI:  No objection, Judge.

 6       THE COURT:  So admitted.

 7       (Defendants' Exhibit 4123 in evidence.)

 8  BY MR. KLEIN:

 9  Q.   So the first email in the chain down below from

10  Chris Cruz to you on Monday, September 8th, 2008.

11       Do you see that?

12  A.   I do, yeah.

13  Q.   All right.

14       And it says:  "Hi, Kim.  Russ Moyer just reconfirmed

15  with me that Brian Marsh has made it clear to him that he is

16  not interested in participating in the speaker bureau anymore

17  if he can't speak off label."

18       Do you see that?

19  A.   I do.

20  Q.   All right.

21       And then let's look at your response in the email

22  above.

23       You respond -- you say, "Chris, Janet, Jennifer."

24       And do you remember who these folks are?

25  A.   Yes.
```

United States District Court
District of New Jersey

1 Q.   Chris, Janet, and Jennifer?

2   What were their roles at the company?

3 A.   Chris and Janet were -- worked with MedEd-Link, Inc.

4 They were -- that was the vendor that conducted -- or

5 logistically organized our speaker training meetings.

6   And Jennifer was from Allied Health Media. She was the

7 lead account person, and they were the vendor -- the vendor

8 who managed the speaker bureau, so helped with travel, setting

9 meals to ensure that they were within compliance, contracts,

10 that kind of thing.

11 Q.   Okay.

12   And we can talk about --

13 A.   Sure.

14 Q.   -- those folks and their roles in a minute.

15   But you say: "Chris, Janet, Jennifer, I understand

16 that Dr. Marsh has RSVP 'd in the affirmative to attend one of

17 the Intelence trainings webcasts this week. From the email

18 below, I should think this will not happen. Please remove him

19 from any future communications about those meetings."

20   And then two paragraphs down from that, you'll see

21 where it says, "Jen, please block Dr. Marsh in the system."

22   So what were you doing there?

23 A.   Well, this was a physician who identified that he would

24 not -- he did not want to present the approved slide deck as

25 it was, and that was the only materials he was permitted to

1   present.

2   So what I did here was communicate with the vendor who

3   was managing the webcast where speakers would be trained to

4   ensure that he did not participate. In the event that he did

5   log in for some reason, he would not get paid for that

6   participation.

7   And then the Jen part was to Jennifer letting her know

8   that he should be blocked in the AHM system so that no rep

9   could request him for a program.

10 Q. Okay.

11   So fair to say this is an example of the company

12 enforcing the ban against off-label speaking?

13 A. Correct.

14 Q. All right.

15   And you talk -- mentioned the vendors, and it sounded

16 like there were a couple of them there.

17   Can you just explain to the jury what the -- what the

18 two vendors were that you mentioned and what their roles were

19 in -- with respect to the speaker program?

20 A. Yep. So MedEd-Link is a company who -- they specialize

21 in -- basically in conducting meetings, so that they would --

22 they would find a venue that was suitable, like a business

23 hotel. They would book the boardroom.

24   They would set the menu so that they adhered to our

25 financial policies, so $25 for breakfast, $50 for lunch,

1   inclusive of taxes and gratuities.

2   They would ensure that each person, speaker invited to

3   participate in the training had a signed contract before they

4   ever attended. They would provide them their check -- their

5   honoraria check for attending speaker training after it was

6   conducted.

7   They would ensure that all of the speakers were present

8   and signed in for the entirety of the speaker training

9   meeting.

10 Q.   Okay.

11   And why did the -- based on your understanding, why did

12 the company engage these vendors? Why didn't it attend to the

13 implementation of the speaker program itself?

14 A.   Well, while our speaker program was relatively small,

15 given the industry -- in the industry, it still was far too

16 many details and far too many people for one marketing person

17 to wrap their arms around.

18   So in order to ensure compliance and that everything

19 was done and done well, there are all kinds of companies that

20 have become experts in doing exactly these kinds of programs.

21 Q.   Okay.

22   So you had the experts to implement the program

23 properly?

24   Is that --

25 A.   Yep, and we interviewed -- for the speaker bureau

 1 management, we interviewed several companies and vetted them

 2 to ensure that their capability met our needs.

 3 Q.   Okay.

 4   If we go to the next page -- I'm sorry. Go back to the

 5 speaker policy.

 6   MR. KLEIN: Defendants' 4006, Mr. Morales. All

 7 right. And on page 4, at the bottom.

 8 BY MR. KLEIN:

 9 Q.   There's a term or a policy on compensation.

10   And it says, "Compensation paid to the speaker should

11 be consistent with fair market value for services and should

12 not take into account the volume of product usage or the

13 amount of prescriptions written by the speaker."

14   In your experience, was the speaker bureau program

15 implemented consistent with that policy?

16 A.   Yes.

17 Q.   Okay.

18   And what -- do you know how the company determined fair

19 market value?

20 A.   Oh, sure. When we were evaluating a roster of speakers,

21 there were a set list of criteria, and we would work again in

22 an interdisciplinary team, so someone from marketing, someone

23 from the clinical or medical affairs team, often health care

24 compliance.

25   We would look at each name and basically look at the

1   resume. So one of them was years in practice, breadth of

2   experience. Were they an academic researcher? Were they in

3   academia? Were they in private practice? Had they published?

4   Were they investigators in clinical trials? That kind of

5   thing.

6   Q.   Okay.

7   And to your understanding did the amounts -- we -- I

8   believe -- correct me if I'm wrong, but I believe there was a

9   range of -- a range of the amount of the honoraria that could

10   be paid to a speaker?

11   A.   Yes. So there was a band, if you will, so fair market

12   value from one speaker to another might vary a little bit

13   based on maybe someone has been in practice for 20 years and

14   they're internationally recognized and they have been

15   conducting research for decades.

16   That kind of person would command likely a higher

17   honoraria than someone who was in a small private practice

18   still managing a lot of HIV patients, but, you know, might

19   work in Santa Fe.

20   Q.   And who would make that determination? Was that you or

21   was that the vendor, if you recall?

22   A.   Oh, no. That would be an internal decision.

23   Q.   An internal decision?

24   A.   Like -- well, between, again, a multidisciplinary group

25   of people, so marketing and health care compliance would

1 ultimately approve.

2 Q.   Got it. Okay.

3   Now, this policy came out in 2005, so shortly before

4 the launch of Prezista.

5   Correct?

6 A.   Yes.

7 Q.   Okay.

8   And before launching the speaker program, was there a

9 needs assessment performed to sort of, you know, set the size

10 and the scope of the program?

11 A.   Yeah, absolutely. So any time you were endeavoring to

12 start or set up a speaker bureau, a comprehensive needs

13 assessment would have to be -- it was basically a rationale

14 for why you wanted to create such a program, conduct such a

15 program.

16   And so we would put that document together, and, again,

17 it would go to health care, compliance, legal, regulatory for

18 review --

19 Q.   Okay.

20 A.   -- and approval ultimately.

21 Q.   And what kinds of things would be considered in

22 connection with the needs assessment?

23 A.   Number of speakers you wanted to train, number of

24 programs you wanted to conduct, geographic scope, that kind of

25 thing.

 1 Q. All right.

 2   And then who -- would there be a person or group that

 3 would review and approve the needs assessment?

 4 A. Yeah. You would submit it to health care compliance or

 5 the SAFE committee.

 6 Q. Okay.

 7   So health care compliance would be one group, and the

 8 SAFE committee?

 9 A. Yeah, sorry. SAFE committee comprised health care

10 compliance, and I think it also -- this was a long time ago.

11 Sorry. I think members of medical affairs might look at it as

12 well, or legal.

13 Q. Okay.

14   And then this is a -- I'm going put on the ELMO a

15 document that our jury has seen a couple of times. It's a

16 demonstrative.

17   MR. KLEIN: Mr. Morales?

18 BY MR. KLEIN:

19 Q. So you'll see on the screen, Ms. Saladana, just a

20 demonstrative that our jury has seen before.

21   But just mapping out, I mean, does this accurately

22 represent, at least at a high level, the different sort of

23 constituencies that were involved in setting up the speaker

24 bureau and selecting speakers?

25 A. Yeah, that looks accurate.

United States District Court
District of New Jersey

 1 Q.   Okay. Okay.

 2   So let's talk about selection of -- selection of

 3 speakers for a minute.

 4   MR. KLEIN: Mr. Morales, if we can go back to the

 5 policy document. So that's D-4006. Go to page 5. Sorry.

 6 Page 7. Sorry. I'm losing count. There we go.

 7 BY MR. KLEIN:

 8 Q.   You see halfway down the page, Ms. Saladana, where it

 9 says, "selection of speakers"?

10 A.   Yep.

11 Q.   All right.

12   And the policy provides "Objective criteria must be

13 developed and documented by marketing for the selection and

14 quantity of speakers. The criteria and qualifications of

15 individual speakers selected must be documented in the SAFE

16 submission."

17   Do you see that?

18 A.   I do.

19 Q.   Okay.

20   And what -- what's the SAFE submission that's referred

21 to there?

22 A.   That would be all of the -- it would be the needs

23 assessment, all of the documentation, and so the -- you

24 mentioned fair market value earlier.

25   There was an -- an online system internally that was

1   developed, and so you would input all of your -- all of your

2   inputs -- sorry -- into that to come up with your fair value

3   calculation.

4   So there were spreadsheets, speaker lists, anything

5   having to -- all of the documentation, you would organize it

6   and submit it.

7   Q.   Got it.

8   And then the next bullet, it talks about speaker

9   selection and qualification, and it lists a number of factors

10   that the assessment should include.

11   Do you see that? Educational background, medical

12   specialty, research, stature in the community, practice focus,

13   experience, presentation skills, availability to speak,

14   et cetera.

15   Do you see that?

16   A.   I do.

17   Q.   Okay.

18   And in your experience, were the speakers on the

19   speaker bureau selected consistent with these criteria?

20   A.   They were.

21   Q.   All right.

22   And you see below it it says, "Selection may not be

23   contingent upon purchasing volume and/or prescriptions of the

24   company products."

25   Do you see that?

United States District Court
District of New Jersey

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 1  A.   I do.

 2  Q.   Okay.

 3       During your time at the company, to your understanding,

 4  were speakers ever selected based on their prescription

 5  volume?

 6  A.   In marketing we didn't look at prescription volume for

 7  that purpose, no.

 8  Q.   Okay.

 9       And when you say marketing, that -- or including the

10  process with the SAFE committee, health care compliance,

11  medical, et cetera?

12  A.   Correct.

13  Q.   Okay.

14       It's fair to say that was not a criteria that they used

15  in selecting speakers for the bureau.

16       Is that right?

17  A.   Right, and in this time, we didn't have an approved

18  product to even look at that kind of information had we wanted

19  to, which we were forbidden to.

20  Q.   Got it.

21       And just in setting up the program, implementing the

22  program, was even one of the purposes of the program to

23  increase the prescriptions of speakers?

24  A.   No.

25  Q.   Okay.
```

1   How would you describe the purpose of the program?

2 A.   The Promotional Speaker Bureau program was designed to

3 train speakers to be able to go out into the community and

4 educate other health care providers, including allied health

5 care providers -- so that would be your nurse practitioners,

6 your nurses, your pharmacists -- about this new product

7 available for the treatment of HIV. That was the purpose.

8 Q.   All right.

9   MR. KLEIN: Mr. Morales, if we can go to the next

10 page.

11 BY MR. KLEIN:

12 Q.   The policy goes on, and there's a -- there's a bullet

13 sort of two-thirds -- or one-third of the way down, that first

14 empty sub-bullet there that says "Speakers must be used a

15 minimum of three times annually to remain a member of the

16 faculty. Exceptions must be reviewed and approved by the

17 SAFE committee."

18   Do you see that?

19 A.   I do.

20 Q.   Now, what was -- what was the reason for that

21 requirement, for requiring three speeches annually?

22 A.   Well, if a speaker wasn't going to be engaged and

23 actively promoting -- going out and conducting these

24 promotional speaker programs, one had to question the utility

25 of spending money to train -- inviting them to a training

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 1  meeting, paying them for attending a training meeting that --

 2  if they weren't going to be speaking, then they shouldn't be

 3  on the speaker bureau.

 4  Q.   And in terms of selecting the speakers, I mean, I think

 5  you alluded to that.  We looked at some policy criteria that

 6  would govern that.

 7       If you see the bottom bullet on the screen right now,

 8  it says, "Field-based staff, either sales or clinical, may not

 9  be responsible for speaker selection.  However, they may

10  provide recommendations for speakers based on the

11  predetermined criteria on request.  The final decision of who

12  is invited to take part in a speaker bureau is determined by

13  marketing management and must comply with SAFE committee

14  recommendations."

15       Do you see that?

16  A.   I do.

17  Q.   Okay.

18       And, again, in practice, was the speaker bureau

19  implemented consistent with that policy directive?

20  A.   It was.

21  Q.   Okay.

22       Maybe we can flesh that out a little bit.

23       So it talks about the sales staff being able to submit

24  recommendations --

25  A.   Uh-huh.
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United States District Court
District of New Jersey

1 Q.   -- for speakers.

2   So how would that process work in practice? So the

3 sales staff might have -- well, first of all, how often was

4 the speaker roster reviewed? Is it reviewed annually? Every

5 two years? Every three years?

6 A.   Typically, annually you would renew your speaker bureau.

7 Q.   Okay.

8   And the -- it says here that the sales staff can make

9 recommendations.

10   So how would that work? Who would they send the

11 recommendations to?

12 A.   Oh, sure.

13   So I would be sitting in marketing, in the office, and

14 I would send an email, let's say, to the district managers.

15 And every district manager would have seven or eight reps, and

16 I would ask them for their input. So could you go out and ask

17 your reps to compile a list of providers they feel would best

18 represent their geography?

19   So because I don't live in New Mexico or Texas or what

20 have you, reps would be involved in the process of making

21 recommendations such that it -- they were recommending folks

22 that they -- they knew to be reputable providers that would be

23 able to cover their geography without making someone travel

24 too much.

25   They would put together their list, we would ask for

United States District Court
District of New Jersey

 1 | that to -- you know, like, level that up to your district

 2 | manager. The district manager would send their list in. I

 3 | would make a big master list, and then myself and a bunch of

 4 | colleagues in the office would evaluate that list.

 5 | MR. KLEIN: And so, Mr. Morales, if we can have the

 6 | ELMO again.

 7 | BY MR. KLEIN:

 8 | Q.   So this would be -- would the groups or the departments

 9 | that are shown on the slide, would they be involved in

10 | evaluating those lists?

11 | A.   Yes.

12 | Q.   Okay.

13 | And how exactly would they evaluate them?

14 | A.   Those fair market -- or sorry, not fair market. Those

15 | criteria. So the person in marketing would be responsible for

16 | compiling all of that information, and it would be a big

17 | spreadsheet, and you would have columns of: Are they in

18 | academic researcher? Or are they, you know, internationally

19 | recognized? Do they -- that kind of thing.

20 | And then you would sit down, and we would ensure that

21 | we had good representation, that it was fair to every

22 | district, you know, that everyone had a similar number of

23 | speakers to represent their geography.

24 | And ultimately, we'd compile all of this information.

25 | It would go to the SAFE committee. The SAFE committee would

 1   review it and/or -- and approve it or ask for more information

 2   or clarifications, that kind of thing.

 3   Q.   Was prescription volumes one of the criteria?

 4   A.   No. No. We didn't look at prescription volumes.

 5   Q.   All right.

 6   So sales teams, did they have visibility into that

 7   process? And did -- well, let me just ask you that first.

 8   Did sales teams have visibility into that evaluation

 9   and decision-making process?

10   A.   Not in any in-depth way. The speaker bureau policy

11   document, they didn't get that, no.

12   Q.   Okay.

13   But, I mean, in terms of the evaluation of the

14   recommended speakers and the decision of who would be on the

15   list, was sales a part of that decision-making process?

16   A.   They did not get into the trenches of that, no.

17   Q.   Okay.

18   So sales could make a recommendation, but is it fair to

19   say that, in terms of the actual criteria that were evaluated

20   to select the speakers and the actual decision-making of

21   around who would be on the speaker bureau, is it fair to say

22   that was not something they were involved in?

23   A.   No. They could make recommendations and that was the

24   extent of it. That's where their role and participation in

25   the process ended.

1 Q.   All right.

2   MR. KLEIN: So, Mr. Morales, if we could go back to

3 the policy, please, 4006.

4 BY MR. KLEIN:

5 Q.   The next section down references "Training of Speakers."

6 It says, "All speakers must be trained on company conduct and

7 conduct prior to speaking on behalf of the company.

8 Documentation of this training must be maintained by the

9 company marketing department."

10   Do you see that?

11 A.   Yes.

12 Q.   Okay.

13   And how is that training delivered to the speakers?

14 A.   Oftentimes it would be live. They would all be gathered

15 in a business hotel, and we would train them in a live

16 environment. Sometimes through our Webex meeting, if -- but

17 that was usually secondary to a live meeting.

18 Q.   And what sorts of things would the training cover?

19 A.   Health care compliance always had a spot for main stage.

20 They would present and present all of the policies that

21 governed their behavior.

22   Medical, medical affairs, clinical partners would get

23 up and provide an overview of the promotional slide deck.

24   Sometimes we'd run our workshops on presentation

25 skills, that kind of thing.

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 1  Q.   Okay.

 2        And why was the -- did the company do that training as

 3  an important component of the speaker bureau?

 4  A.   Yes.  It was a regulatory and legal mandate.  We had to

 5  -- absolutely had to familiarize the speakers on the approved

 6  promotional slide deck.

 7  Q.   All right.

 8        MR. KLEIN:  Mr. Morales, if we could pull up, just

 9  for the witness and counsel, Defendants' Exhibit 4131.

10  BY MR. KLEIN:

11  Q.   Ms. Saladana, do you see the document there on the screen

12  for you?

13  A.   I do.

14  Q.   All right.

15        Is -- is this an example of a speaker training deck

16  that would have been used?

17  A.   Yes.

18  Q.   Okay.

19        MR. KLEIN:  Your Honor, we move to admit Defendants'

20  4131.

21        MR. WIRMANI:  No objection.

22        THE COURT:  So admitted.

23        (Defendants' Exhibit D-4131 in evidence.)

24        MR. KLEIN:  So if we can put that up on the screen,

25  Mr. Morales.
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 1  BY MR. KLEIN:

 2  Q.   So it says, "Promotional Speaker Bureau training,

 3  November 2008."  And we can just flip through it, or at least

 4  a few bits of it.

 5       So on Slide 3, there's a --

 6          MR. KLEIN:  Can we go back?  Perfect.

 7  BY MR. KLEIN:

 8  Q.   It says, "Speaker Compliance Guidelines."  And there's

 9  several bullets there about general sort of compliance topics.

10       And then the next slide has more compliance guidelines,

11  a lot of which look to track the speaker policy that we were

12  just looking at.

13       Is that fair?

14  A.   Uh-huh.

15  Q.   So was compliance a significant component of the speaker

16  training?

17  A.   Yep.  Someone from HCC would typically get up and present

18  all of the rules and regulations that govern their behavior at

19  a speaker program for about an hour.  And it was serious.  I

20  mean, I don't mean to make light of it.  It was just -- you

21  know, the content is dry, but it was done.

22  Q.   All right.

23       Did you ever attend the speaker trainings?

24  A.   Oh, yes.

25  Q.   How often?
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United States District Court
District of New Jersey

1 A.   Well, over the course of a number of years, maybe four,

2 five times. So, yeah, we would often do an east and a west,

3 so we weren't flying -- to reduce expenses. So we weren't

4 flying people across the country and using up a whole bunch of

5 people's time.

6   So we would maybe do one in the east and one in the

7 west. So several. Many, many, many.

8 Q.   Okay.

9   Many, many. All right.

10   And just in your experience, how was the training

11 typically received by the doctors who were participating?

12 A.   It was -- I think it was very well received. They, you

13 know -- I mean, most speakers understood we -- our company was

14 no different than other companies that were governed by

15 FDA/DDMAC. We all, you know, required the same things of our

16 speakers, and that was, you know, you have to use this deck.

17 And that was just the way the governance worked.

18 Q.   All right. Very good.

19   So you mentioned earlier that you thought Tibotec's

20 speaker program was small relative to some of the others that

21 you are familiar with. What did you mean by that? Why did

22 you consider it small?

23 A.   Well, the number of providers managing people living with

24 HIV in the U.S. at the time was around 5,000. And, you know,

25 if you look at diabetes or cardiology, those kinds of

 1 therapeutic areas, they are far larger. So they would have

 2 many, many -- hundreds of speakers and run thousands of

 3 programs.

 4   But, again, the therapeutic areas is -- involves a lot

 5 more people.

 6 Q. Okay.

 7   And there were -- I think during the trial we've heard

 8 reference to a few different types of speaker programs. So

 9 we've been talking about promotional speaker programs to this

10 point.

11   Is that correct?

12 A. Correct.

13 Q. Okay.

14   What about community or disease-state awareness

15 programs? Are you familiar with those?

16 A. I am.

17 Q. Okay.

18   How do those differ from promotional speaker programs?

19 A. Well, a disease-state program wouldn't mention any drugs

20 at all, wouldn't mention any treatment typically, unless it

21 was at a very top level, like the classes of drugs available

22 to treat a certain condition. But they were all about, you

23 know, HIV 101, basically. Teaching people what the condition

24 was, how it affected the human body.

25 Q. Those were disease-state programs?

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 1  A.    Those, yeah.

 2  Q.    And what about community speaker programs?

 3  A.    I'm not as familiar with those.  I didn't work on the

 4  community speaker bureau that I can recall.

 5         But a community speaker bureau, it would have likely

 6  involved the community liaisons, and they would go out and

 7  educate -- or the speakers would go out and educate community

 8  service organizations.  So there are all kinds of support

 9  groups throughout the U.S. and Canada that support people

10  living with HIV and AIDS and seek to educate them and link

11  them to resources.

12  Q.    Okay.

13         And so those -- I mean, it sounds like those programs

14  are quite different from promotional speaker programs.

15         Would that -- would that be fair to say?

16  A.    In content, yes.  Absolutely.

17  Q.    Okay.

18         And -- well, okay.  We'll leave it there.

19  A.    Okay.

20  Q.    So we've also heard during the trial references to return

21  on investment or ROI analysis.  So I want to talk about that

22  for a minute.

23         Do you remember that being applied to promotional

24  speaker programs at any time?

25  A.    I do.
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United States District Court
District of New Jersey

1 Q.   Okay.

2   And would the return on investment, would it measure

3 the return on the speaker fee paid to the speaker, or would it

4 measure the return on the amount spent on the program based on

5 the attendees of the program?

6 A.   The return on investment analysis we conducted would

7 always focus on the influence those programs had on people who

8 attended the program. So did they behave differently after

9 they attended a program and became aware that Prezista was

10 even available.

11 Q.   Okay.

12   Were you ever aware of an ROI analysis focused on the

13 speakers themselves?

14 A.   That was forbidden. No, we didn't do that.

15 Q.   Okay.

16   I want to show you a document we've seen in the trial a

17 couple times.

18   MR. KLEIN: Relators' Exhibit 316. I believe it's

19 already in evidence.

20   All right. This document here is page 1.

21   Mr. Morales, if we could just go to page 2.

22 BY MR. KLEIN:

23 Q.   It's titled "New England Speaker Sales Performance."

24   Do you see that lists some speakers, lists

25 prescriptions?

United States District Court
District of New Jersey

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 1            Is this an ROI analysis?

 2   A.   No, it's a -- no.

 3   Q.   Okay.

 4            I mean, is it fair to say, though, that the company

 5   would have had prescription information on the speakers in the

 6   bureau?

 7   A.   On the speakers, no.

 8   Q.   Well, let me just break it -- take it step-by-step.

 9            So the company worked with a lot of doctors.

10            Correct?

11   A.   Uh-huh.

12   Q.   Okay.

13            And some of those doctors might be speakers.

14            Correct?

15   A.   Yes, the two things were not mutually exclusive.

16   Q.   Okay.

17            So in the normal course of events, would the company

18   receive or collect data on the prescriptions of the doctors

19   that it worked with, whether they were speakers or not?

20   A.   Yes.

21   Q.   Okay.

22            So is it fair to say, in the normal course, the company

23   would have data on the speaker prescriptions just like they

24   would have data on the prescriptions of any other doctor that

25   was detailed by its sales reps?
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United States District Court
District of New Jersey

 1   A.   That's fair to say.

 2   Q.   Okay.

 3   But that's -- is that the same thing as an ROI

 4   analysis, or is that just prescription data?

 5   A.   No. And this isn't an ROI analysis.

 6   Q.   Okay.

 7   Well, let's look at another document.

 8   MR. KLEIN: Mr. Morales, just for the witness and

 9   counsel, please.

10   D-4006. Excuse me. D-4066.

11   BY MR. KLEIN:

12   Q.   Ms. Saladana, you should see on your screen a -- it looks

13   like a PowerPoint presentation. It says, "Speaker Program

14   Analysis." It's authored by you and one other individual.

15   Do you see that?

16   A.   Yes, I do.

17   Q.   Okay.

18   MR. KLEIN: Your Honor, we move to admit Defendants'

19   Exhibit D-4066.

20   MR. WIRMANI: No objection, Judge.

21   THE COURT: So admitted.

22   (Defendants' Exhibit D-4066 in evidence.)

23   BY MR. KLEIN:

24   Q.   If we flip through, there are a number of analyses on the

25   slides in this deck. We'll just flip through them page by

1   page.

2   MR. KLEIN: And let's go to page 8. Sorry. Slide 8.

3   Maybe the next one -- there you go. All right.

4   BY MR. KLEIN:

5   Q.   So are these sorts of analyses in this deck -- is this

6   the type of ROI analysis that typically would be conducted on

7   the speaker programs?

8   A.   It is, yes.

9   Q.   Okay.

10   And this slide actually says there seems to be no

11 direct link between the number of speaker programs and total

12 prescriptions in subsequent months.

13   Do you see that?

14 A.   Yes. As a marketer, it was very depressing. But yes.

15 Q.   Okay.

16   And -- but I take it, based on your testimony, all this

17 information on the return on investment analysis was focused

18 on the attendees of the speaker programs?

19 A.   That's right.

20 Q.   Okay.

21   And, actually, if we go -- if we skip ahead to

22 Slide 13, we can see "Observations." And the second bullet

23 says, "Number of programs do not correlate to prescription

24 Rx," meaning prescription, "behavior post speaker program with

25 the exception of November."

United States District Court
District of New Jersey

1   Again, it doesn't look like you're finding a link

2   between the programs and the attendees' prescriptions.

3   Is that fair?

4   A.   Sadly, that is a fair statement, yes.

5   Q.   And then the sub-bullet says, "Largest increase in total

6   prescriptions for those attending the November programs. 93

7   programs run in November."

8   And then the bullet below it: "However, some speakers

9   have a bigger affect than others on program attendees."

10   Do you see that?

11   A.   I do.

12   Q.   Okay.

13   And so does this, again, illustrate that the ROI

14   analysis that the company was performing was focused on

15   attendees and not speakers?

16   A.   Correct.

17   Q.   And what was the purpose of that ROI analysis? How would

18   the company use that information?

19   A.   Well, at a very general level it was to just Friday the

20   expense of actually conducting a promotional speaker program

21   because if it wasn't, if it wasn't generating awareness for

22   our product, it wasn't a very efficient or effective use of

23   resources. And these were not inexpensive programs to set up

24   and run.

25   Does that answer your question?

1   Q.   It does.

2   A.   In part? Sorry. I forgot the second part of your

3   question.

4   Q.   No, no. That was it.

5   A.   Okay.

6   Q.   You paused. Did you have more to say on that or no?

7   A.   No.

8   Q.   Very good.

9   One of the provisions in the policy required that there

10   would be a contract with the speakers.

11   Is that true?

12   A.   Absolutely.

13   Q.   Okay.

14   And let's see if we can just take a look at a contract,

15   an example of this -- one of these contracts very quickly.

16   Just to get a feel for the terms.

17   A.   You bet.

18   Q.   All right.

19   MR. KLEIN: So, Mr. Morales, just for the witness and

20   counsel, Defendants' Exhibit 4187, please.

21   BY MR. KLEIN:

22   Q.   Do you see the document on the screen, Ms. Saladana?

23   A.   I do.

24   Q.   All right.

25   Is that a speaker contract?

United States District Court
District of New Jersey

1 A.   It looks like one, yes.

2 Q.   And you can see actually it's the contract for a doctor

3 named Dr. Ricky Hsu, who I think this jury is familiar with.

4   Do you see that?

5 A.   Yes, I do.

6 Q.   Okay.

7   MR. KLEIN: Your Honor, move to admit Defendants'

8 Exhibit 4187.

9   MR. WIRMANI: No objection.

10   THE COURT: So admitted.

11   (Defendants' Exhibit D-4187 in evidence.)

12 BY MR. KLEIN:

13 Q.   Over your time at the company, were the -- did the terms

14 of the speaker contracts remain substantially the same?

15 A.   Yes, they were consistent.

16 Q.   Okay.

17   And so there are several provisions in the contract.

18 And just to point out a few very quickly here.

19   So Provision Number 3, "Speaker training." The speaker

20 agrees that they must attend the training" including the

21 compliance training we just talked about.

22   Do you see that?

23 A.   I do.

24 Q.   All right.

25   And then under Provision Number 4, the speaker has to

United States District Court
District of New Jersey

 1   conduct "a minimum of three promotional programs during the

 2   year."

 3   Do you see that?

 4   A.   Yes, I do.

 5   Q.   Okay.

 6   And then under 4(i), the speaker understands that the

 7   slide lecture kit has been pre-approved by the review

 8   committee and will not modify the slide and lecture kit.

 9   Do you see that?

10   A.   Yes.

11   Q.   Okay.

12   So is it fair to say that the terms of the contract

13   that the speakers were bound to follow, you know, tracked many

14   of the compliance policy provisions that we looked at in the

15   speaker policy?

16   A.   Absolutely.

17   Q.   Okay.

18   If you go to page --

19   MR. KLEIN: Mr. Morales, if we can go to page 3 of

20   the document.

21   BY MR. KLEIN:

22   Q.   There's a provision, Number 6, on fair market value.

23   So "You and the company agree and acknowledge that the

24   compensation represents fair market value for speaker training

25   and services and has not been determined in a manner that

United States District Court
District of New Jersey

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 1  takes into account the volume or value of any business

 2  otherwise generated between you and the company and shall not

 3  obligate you to purchase, use, recommend, or arrange for the

 4  use of any products of the company or its affiliates."

 5       Do you see that?

 6  A.   I do.

 7  Q.   Okay.

 8       In your experience, did the doctors who signed these

 9  contracts understand and abide by these provisions?

10  A.   Absolutely.

11  Q.   And then in the -- paragraph 8 relates to "Compliance

12  With Company Requirements."

13       And if you go to -- onto the next page, there's a

14  provision that says, You agree that your representations

15  regarding any products of the company, including, without

16  limitation, relating to use, safety effectiveness of the

17  products and/or actual potential clinical outcomes which have

18  been covered can be expected use of the product, shall be

19  within the FDA-approved label for the products and shall be

20  fairly balanced.

21       Do you see that?

22  A.   I do.

23  Q.   Okay.

24       And in your experience and understanding, did the

25  physicians comply with that?
```

1 A.   Yes.

2 Q.   All right.

3   MR. KLEIN: Your Honor, we're probably at a good

4 stopping point here.

5   THE COURT: You have another ten minutes. You don't

6 want them?

7   MR. KLEIN: Well, no. I'm just saying --

8   THE COURT: Oh, you think you're going to hit another

9 topic that's going to run too long?

10   MR. KLEIN: Maybe, yes.

11   THE COURT: All right. Well, then, let's do that.

12 Let's close it out for the day. It's only a few more minutes.

13   All right, folks. We're going to end for today.

14 Tomorrow we will be ready to proceed at 9. Is that right?

15   And my understanding is we're only going to 4 o'clock

16 tomorrow. So we'll make those adjustments. The counsel be

17 aware.

18   All right. Well, then, let's get the jurors out. I do

19 want to speak to counsel after the jurors are excused.

20   THE DEPUTY COURT CLERK: All rise.

21   (The jury is excused.)

22   THE COURT: Ms. Saladana, you're excused, temporarily

23 excused. You need to be back here 9 a.m. tomorrow. All

24 right?

25   Folks, do we need to talk about anything? I've got

United States District Court
District of New Jersey

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 1  something, but do we need to chat about anything -- you guys

 2  can sit.  But do we need to speak about anything before we

 3  adjourn for the day?

 4          MR. MARKETOS:  Not from the Relators, Your Honor.

 5          MS. BROWN:  Not from our point of view, Your Honor.

 6          THE COURT:  All right.  Well, then, let's do this.  I

 7  want to at least address tomorrow morning, the discovery

 8  violation and the request for the adverse inference from

 9  Relators' counsel.

10      So 8:30 maybe cutting it a little tight because I don't

11  know how much needs to be said about that.  So should we meet

12  at eight o'clock on the record, just to make sure we have time

13  to address that issue?

14          MR. MARKETOS:  Yes, Your Honor, please.

15          THE COURT:  Ms. Brown?

16          MS. BROWN:  Yep.  That'd be fine.

17          THE COURT:  All right.  Secondly, be prepared,

18  although I'm not sure we'll get to it tomorrow, but be

19  prepared to address the waiver of privilege issue as well.

20  I'm going to put eyes on your submissions tonight.

21      I don't know if I really need to review in camera

22  documents that have been withheld as privileged in order to

23  assess whether the privilege has been waived.  So depending on

24  my thought about that later tonight, I may not have to go

25  through all those documents for purposes of addressing the
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 1 waiver issue, but be prepared that if we have time, I may want

 2 to address both tomorrow because I don't want to get to the

 3 end of this week with those issues outstanding.

 4   So at the bare minimum, we're going to address the

 5 discovery -- the compliance investigation discovery issue

 6 along with the remedy that Relators' counsel requested. We

 7 may get into the privilege issue. And if we don't, that may

 8 get tabled for another day, but let's see.

 9   Other than that, what else? Just a reminder that we're

10 going until 4.

11   Ms. Brown, who are the witnesses for tomorrow? I know

12 you guys are probably talking, but I have no idea.

13   Who comes after Ms. Saladana?

14   MS. BROWN: Sure. So we have Candice Long who comes

15 after Ms. Saladana. And we're speaking with Mr. Russ. We're

16 frankly moving faster than we imagined, Your Honor, so we may

17 need to quickly get with them tonight and have another witness

18 on standby in case those two finish.

19   THE COURT: Do that then, because I want to use the

20 time -- look, if we end up getting -- if you all rest it the

21 11th, so be it.

22   MS. BROWN: Sure.

23   THE COURT: But I want to use the time wisely. I

24 don't mind if we're at five or ten minutes like what Mr. Klein

25 did today. We're close to the end of the day and you think

United States District Court
District of New Jersey

1   that switching topics really isn't going to be helpful to the

2   jury, I'll hear from you.

3   But unless we're in that five-to-ten-minute window, I

4   really do want you having witnesses on deck.

5   Make sense?

6   MS. BROWN: And we will have somebody on standby.

7   THE COURT: So at least Ms. Saladana and then

8   Ms. Long, but there could be a third witness that you need to

9   line up, depending on how quickly this goes.

10   MS. BROWN: Yes. Exactly, Your Honor.

11   THE COURT: All right. What else? Anything, folks?

12 Otherwise, we're done for the day.

13   MR. MARKETOS: Not from us, Your Honor. Thank you.

14   THE COURT: All right. Thanks, everybody.

15   Ms. Brown, nothing else?

16   MS. BROWN: No. Thank you, Your Honor.

17   THE COURT: All right. Be well.

18   (Court adjourned at 4:55 p.m.)

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United States District Court
District of New Jersey

1   FEDERAL OFFICIAL COURT REPORTER'S CERTIFICATE.

2   -

3

4   I certify that the foregoing is a correct transcript from

5   the record of proceedings in the above-entitled matter.

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8   I

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10

11   /S/ Megan McKay-Soule, RDR, CRR   June 3, 2024

12   Court Reporter   Date

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United States District Court
District of New Jersey

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$1,200 [2] - 5437:18, 5438:1
$10 [1] - 5440:1
$14 [1] - 5425:1
$17 [1] - 5425:7
$2,500 [4] - 5575:19, 5576:21, 5595:4, 5597:25
$2.35 [1] - 5414:7
$2.84 [1] - 5474:23
$2.90 [2] - 5473:8, 5473:13
$2.95 [1] - 5484:14
$200 [2] - 5625:5, 5627:22
$25 [1] - 5690:25
$250,000 [1] - 5432:6
$327 [1] - 5426:11
$4,000 [1] - 5474:11
$50 [1] - 5690:25
$500,000 [1] - 5589:23
$700 [3] - 5541:15, 5625:3
$750 [2] - 5474:4, 5474:5
$825 [1] - 5587:12
$9 [1] - 5429:9

'

'05 [1] - 5676:6
'09 [1] - 5676:6
'10 [1] - 5428:20
'12 [1] - 5566:15
'13 [1] - 5566:15
'14 [1] - 5566:15
'22 [1] - 5403:8
'84 [1] - 5403:3
'85 [1] - 5403:3

/

/S [1] - 5723:11

0

0.0 [2] - 5432:20, 5433:9
08608 [1] - 5378:9

1

1 [30] - 5416:8, 5428:22, 5428:25, 5429:3, 5429:4, 5429:5, 5429:8, 5429:9, 5429:12, 5429:25, 5435:21,

5435:23, 5455:7, 5460:3, 5460:9, 5460:13, 5460:18, 5461:19, 5598:14, 5599:3, 5599:4, 5604:1, 5623:13, 5638:15, 5710:20
1,000 [1] - 5549:25
1,014 [4] - 5468:4, 5468:10, 5596:1, 5596:2
1,040 [1] - 5523:11
1,200 [3] - 5615:17, 5615:18, 5615:21
1,208 [1] - 5600:19
1,600 [1] - 5455:21
1,620 [1] - 5455:20
1-plus [1] - 5599:7
1.02 [1] - 5425:23
1.1 [2] - 5427:4, 5614:25
1.2 [2] - 5459:21, 5460:17
1.3 [1] - 5434:13
1.4 [1] - 5661:10
1.6 [1] - 5667:14
1.65 [6] - 5435:16, 5435:17, 5435:19, 5442:13, 5442:17, 5458:13
1.9 [4] - 5487:25, 5488:3, 5488:12
1/30 [1] - 5429:7
1/300 [1] - 5429:8
10 [6] - 5452:11, 5461:19, 5476:18, 5524:3, 5601:14, 5623:13
10,000 [2] - 5448:4, 5448:7
10.2 [2] - 5433:13, 5433:15
10.4 [1] - 5435:9
100 [20] - 5429:4, 5437:15, 5438:2, 5438:21, 5439:6, 5460:3, 5460:13, 5466:25, 5522:5, 5527:18, 5534:13, 5545:11, 5545:13, 5545:14, 5545:24, 5546:5, 5623:12, 5624:9, 5625:9, 5627:17
100,000 [4] - 5437:15, 5507:23, 5510:16, 5551:17
100-plus [2] - 5417:4, 5600:16
101 [1] - 5708:23

102 [2] - 5438:9, 5438:20
11 [9] - 5428:10, 5429:9, 5429:23, 5461:14, 5461:22, 5462:15, 5553:4, 5553:6, 5553:7
11.2 [2] - 5450:7
11.22 [1] - 5450:9
110 [2] - 5476:13, 5476:20
112,731 [1] - 5491:18
11:17 [1] - 5494:18
11:19 [1] - 5497:6
11:50 [1] - 5524:25
11:52 [1] - 5527:1
11th [2] - 5384:8, 5721:21
12 [6] - 5636:12, 5656:15, 5656:16, 5657:16, 5657:20, 5658:22
12:30 [1] - 5559:4
12th [4] - 5384:4, 5384:5, 5384:10, 5386:24
13 [1] - 5713:22
13.2 [1] - 5448:3
13.72 [1] - 5477:25
135 [2] - 5467:13, 5602:22
13th [1] - 5384:10
14.6 [1] - 5456:11
149 [1] - 5628:10
15 [9] - 5378:5, 5397:7, 5397:8, 5402:18, 5402:22, 5476:18, 5524:3, 5558:13, 5616:5
150 [1] - 5589:7
16.4 [2] - 5489:3, 5489:8
17 [3] - 5414:19, 5452:12, 5460:10
18 [2] - 5381:6, 5605:4
18.1 [1] - 5453:5
183 [3] - 5438:2, 5438:21, 5439:20
183,000 [1] - 5439:18
19 [1] - 5491:23
19-plus [1] - 5601:23
1973 [1] - 5626:6
1978 [1] - 5401:24
1980 [1] - 5401:24
1980s [1] - 5404:8
1984 [1] - 5403:2
1986 [1] - 5431:24
1998 [2] - 5672:8, 5672:9
1:17 [1] - 5559:4

1:47 [1] - 5583:25
1:50 [1] - 5586:14

2

2 [10] - 5455:7, 5460:10, 5462:5, 5474:19, 5599:3, 5599:4, 5604:1, 5639:19, 5678:13, 5710:21
2,000 [5] - 5542:20, 5543:13, 5547:6, 5550:6, 5550:13
2,355 [1] - 5600:16
2.6 [1] - 5473:10
2.95 [1] - 5483:21
20 [12] - 5381:5, 5383:18, 5392:1, 5403:25, 5458:25, 5460:3, 5460:9, 5605:3, 5609:23, 5673:17, 5673:18, 5693:13
20,000 [1] - 5447:25
200 [5] - 5589:2, 5589:7, 5589:22, 5590:9, 5596:3
200,000 [1] - 5504:9
200-plus [2] - 5600:19
2000 [2] - 5650:17, 5672:8
2005 [7] - 5673:20, 5673:21, 5675:11, 5675:14, 5676:19, 5677:23, 5694:3
2006 [33] - 5413:25, 5414:6, 5414:12, 5417:8, 5418:21, 5424:17, 5428:13, 5428:19, 5459:3, 5469:11, 5480:5, 5480:9, 5484:10, 5533:14, 5533:21, 5535:14, 5564:5, 5564:13, 5565:6, 5575:16, 5575:21, 5576:21, 5591:2, 5604:20, 5608:19, 5609:6, 5609:11, 5629:17, 5637:8, 5678:4, 5682:10, 5687:20
2007 [3] - 5566:21, 5675:15, 5676:3
2008 [6] - 5415:17, 5428:20, 5478:15, 5481:12, 5688:10, 5706:3
2009 [5] - 5565:15,

5565:24, 5566:14, 5676:3, 5676:4
201 [1] - 5601:11
2010 [1] - 5565:20
2011 [18] - 5414:18, 5473:6, 5564:8, 5566:15, 5571:17, 5649:7, 5649:15, 5649:17, 5649:23, 5650:1, 5650:15, 5650:16, 5651:3, 5651:20, 5651:25, 5654:10, 5655:25, 5670:1
2012 [37] - 5474:14, 5476:21, 5637:10, 5637:15, 5638:3, 5638:8, 5643:12, 5644:18, 5644:23, 5645:21, 5645:25, 5646:4, 5646:15, 5647:22, 5648:24, 5649:1, 5649:6, 5649:15, 5649:16, 5649:24, 5650:8, 5650:11, 5650:12, 5650:15, 5651:19, 5652:5, 5652:10, 5652:11, 5654:5, 5655:25, 5656:2, 5659:1, 5660:9, 5660:20, 5664:25, 5669:19, 5670:1
2013 [2] - 5474:22, 5608:19
2014 [35] - 5414:1, 5414:6, 5414:18, 5415:18, 5417:8, 5424:18, 5425:21, 5426:18, 5426:20, 5426:21, 5427:10, 5427:15, 5428:13, 5459:3, 5469:11, 5480:6, 5480:8, 5480:10, 5484:10, 5499:10, 5535:14, 5544:17, 5560:24, 5561:3, 5561:11, 5561:22, 5562:1, 5564:10, 5565:20, 5604:20, 5629:13, 5629:17, 5630:3, 5630:11, 5637:9
2016 [1] - 5480:8
2020 [4] - 5589:1, 5589:5, 5589:22, 5590:16
2022 [1] - 5403:7
2024 [5] - 5378:10, 5380:3, 5475:23,

5605:3, 5723:11
2030 [1] - 5616:6
21 [1] - 5605:4
21.48 [1] - 5435:19
219,000 [1] - 5419:24
22,000 [2] - 5432:4, 5432:5
22.3 [1] - 5450:8
23 [1] - 5548:1
24 [2] - 5428:9, 5452:12
24th [1] - 5682:10
25 [3] - 5381:7, 5383:13, 5383:18
25,000 [3] - 5459:9, 5459:16, 5459:17
25,136 [1] - 5459:6
25-plus [1] - 5600:8
25.6 [1] - 5414:19
250,000 [1] - 5432:10
250-plus [1] - 5600:23
26 [14] - 5450:14, 5504:20, 5505:23, 5505:24, 5506:12, 5506:15, 5506:17, 5507:2, 5507:14, 5507:15, 5547:17, 5548:11, 5548:23, 5581:23
275 [1] - 5611:20
28.2 [1] - 5457:22
29 [2] - 5628:13, 5628:16
29,000 [1] - 5626:11
290,000 [1] - 5626:10
2:23 [1] - 5616:23
2:25 [1] - 5619:5

3

3 [19] - 5378:10, 5380:2, 5416:19, 5455:8, 5474:16, 5474:19, 5517:16, 5584:13, 5584:25, 5585:23, 5585:24, 5587:4, 5604:1, 5678:15, 5685:7, 5706:5, 5716:19, 5717:19, 5723:11
3,187 [1] - 5600:12
3,500 [1] - 5474:11
3,600 [1] - 5504:8
3,680 [1] - 5600:8
3-plus [1] - 5434:14
30 [4] - 5392:20, 5403:25, 5448:9, 5623:12
30-plus [1] - 5624:24
30.2 [1] - 5451:25

300 [14] - 5428:22, 5428:25, 5429:4, 5429:5, 5429:8, 5429:12, 5433:6, 5434:13, 5437:8, 5439:7, 5441:4, 5441:10, 5452:2, 5624:9
300,000 [7] - 5420:1, 5420:4, 5626:2, 5626:6, 5626:7, 5626:12, 5626:18
300-plus [2] - 5459:1, 5601:1
3005 [1] - 5379:12
302 [1] - 5435:23
304 [2] - 5452:2, 5459:16
31 [5] - 5428:11, 5429:1, 5429:3, 5429:16, 5458:14
31.9 [1] - 5458:13
316 [1] - 5710:18
31st [4] - 5499:10, 5560:24, 5561:11, 5562:1
32.2 [1] - 5455:6
32.4 [1] - 5489:11
320 [1] - 5434:14
321 [3] - 5425:20, 5425:23, 5434:14
324 [1] - 5567:22
327 [2] - 5425:22, 5427:10
327.2 [8] - 5426:13, 5427:25, 5428:3, 5480:23, 5490:8, 5491:6, 5492:10, 5493:12
328 [3] - 5466:10, 5597:15, 5598:16
33 [2] - 5442:7, 5517:3
335 [2] - 5429:15
34 [1] - 5614:25
35 [2] - 5607:16, 5625:13
350-plus [1] - 5601:4
36 [1] - 5430:9
360 [2] - 5410:23, 5601:7
361.9 [5] - 5491:7, 5491:8, 5491:14, 5493:3, 5493:25
38 [1] - 5445:7
38,000 [6] - 5419:25, 5444:21, 5444:22, 5446:2, 5446:3, 5615:22
390,000 [3] - 5614:25, 5625:1, 5625:2

392,000 [1] - 5427:5
3:12-cv-07758-ZNQ-JBD [1] - 5378:4
3:17 [1] - 5649:22
3:19 [1] - 5651:13

4

4 [13] - 5381:6, 5434:14, 5455:8, 5584:13, 5584:25, 5585:15, 5585:19, 5585:23, 5585:25, 5692:7, 5716:25, 5719:15, 5721:10
4(i [1] - 5717:6
4,157 [1] - 5600:5
4,439 [1] - 5600:2
4,925 [2] - 5476:14, 5476:16
4.3 [1] - 5474:15
4.9 [1] - 5435:9
40 [4] - 5570:5, 5570:7, 5622:5, 5626:11
40-plus [2] - 5403:9, 5419:24
400 [5] - 5455:8, 5455:12, 5455:13, 5456:5, 5528:11
400-plus [2] - 5601:7, 5601:8
4006 [3] - 5379:13, 5692:6, 5704:3
4019 [3] - 5379:14, 5681:25, 5682:18
402 [1] - 5378:9
4066 [1] - 5379:17
4123 [4] - 5379:15, 5687:13, 5688:4, 5688:7
4131 [3] - 5379:16, 5705:9, 5705:20
414.3 [5] - 5487:20, 5487:24, 5488:3, 5488:5, 5490:3
4187 [3] - 5379:18, 5715:20, 5716:8
43 [2] - 5400:7, 5400:10
435,042 [2] - 5480:17, 5492:17
44 [3] - 5547:12, 5547:16, 5682:5
446 [1] - 5491:12
446.7 [4] - 5485:3, 5485:14, 5490:8, 5491:13
45 [4] - 5558:5, 5559:1, 5600:18,

5682:5
45-minute [1] - 5641:24
46-plus [1] - 5491:11
47 [1] - 5682:5
48 [1] - 5682:5
481,265 [1] - 5493:17
49 [1] - 5623:19
491 [1] - 5601:4
4:55 [1] - 5722:18

5

5 [8] - 5455:8, 5460:13, 5460:18, 5474:10, 5474:19, 5668:16, 5686:16, 5696:5
5,000 [5] - 5476:20, 5597:15, 5602:1, 5676:21, 5707:24
5,000-plus [1] - 5597:3
5,177 [11] - 5466:15, 5567:22, 5568:2, 5598:7, 5598:19, 5599:24, 5616:2, 5616:4, 5624:6, 5630:22, 5631:25
5.61 [1] - 5477:1
50 [19] - 5389:5, 5389:11, 5390:23, 5393:18, 5434:10, 5437:15, 5438:1, 5438:7, 5438:20, 5439:6, 5456:8, 5457:7, 5457:8, 5458:24, 5466:25, 5531:23, 5579:3, 5626:6
50(b [1] - 5389:16
50,000 [3] - 5437:14, 5437:18, 5438:9
50-plus [3] - 5434:7, 5600:12
500-plus [1] - 5601:11
51 [1] - 5460:16
52 [1] - 5571:11
5398 [1] - 5379:4
54,000 [1] - 5434:5
5497 [1] - 5379:4
55,000 [2] - 5462:6, 5462:8
55,879 [1] - 5462:6
5517 [1] - 5379:12
5594 [1] - 5379:5
56 [2] - 5596:25, 5598:7
5636 [1] - 5379:6
5653 [1] - 5379:6

5668 [1] - 5379:7
5671 [1] - 5379:8
5677 [1] - 5379:13
5682 [1] - 5379:14
5688 [1] - 5379:15
5705 [1] - 5379:16
5712 [1] - 5379:17
5716 [1] - 5379:18
59 [5] - 5508:4, 5572:7, 5572:10, 5572:20, 5572:21
593,996 [2] - 5485:15, 5485:18
597.6 [1] - 5415:19

6

6 [3] - 5480:10, 5495:10, 5717:22
6,000 [1] - 5626:11
6.2 [1] - 5407:25
6.3 [9] - 5466:7, 5466:10, 5466:14, 5560:18, 5568:2, 5598:19, 5599:5, 5599:19, 5601:22
60 [4] - 5572:10, 5572:16, 5572:22, 5627:17
600 [2] - 5378:17, 5415:19
600,000 [3] - 5485:14, 5540:5, 5628:6
6029-A [1] - 5661:10
620 [1] - 5539:18
620,000 [4] - 5416:24, 5417:9, 5454:20, 5539:17
63 [1] - 5508:1
644 [1] - 5601:1
65 [5] - 5461:3, 5461:25, 5462:6, 5624:23, 5625:11
65.64 [1] - 5461:15
680 [1] - 5495:10
69 [1] - 5462:15
690 [3] - 5378:24, 5474:4, 5474:5
696 [1] - 5539:19

7

7 [4] - 5428:19, 5543:12, 5611:19, 5696:6
7.2 [1] - 5407:25
7.7 [1] - 5473:10
70 [4] - 5462:18, 5531:22, 5608:24, 5627:17

5464:19, 5475:10,
5475:12, 5518:10,
5532:16, 5594:22,
5595:6, 5603:24,
5603:25, 5604:12,
5714:9
affected [2] - 5631:11,
5708:24
affiliates [1] - 5718:4
afraid [4] - 5667:3,
5667:4, 5667:6,
5667:11
afternoon [6] -
5636:5, 5636:6,
5653:3, 5653:4,
5671:6, 5671:8
age [1] - 5517:21
agencies [1] - 5611:5
aggregated [1] -
5626:22
aging [1] - 5543:4
ago [12] - 5420:25,
5489:24, 5553:8,
5604:23, 5609:23,
5616:15, 5625:25,
5636:20, 5656:15,
5656:16, 5658:22,
5695:10
agree [23] - 5444:18,
5498:11, 5501:6,
5501:10, 5501:14,
5503:11, 5503:23,
5504:7, 5507:15,
5516:10, 5519:19,
5523:10, 5526:24,
5539:25, 5545:19,
5550:17, 5551:10,
5553:20, 5588:2,
5591:8, 5617:25,
5717:23, 5718:14
agreed [4] - 5389:11,
5510:11, 5527:21,
5529:13
agrees [3] - 5577:15,
5577:16, 5716:20
ahead [6] - 5549:3,
5553:10, 5598:6,
5611:22, 5616:6,
5713:21
AHM [1] - 5690:8
Aid [1] - 5626:10
aided [1] - 5378:25
AIDS [4] - 5517:11,
5522:19, 5523:14,
5709:10
aimed [2] - 5476:1,
5476:3
ain't [1] - 5621:15
air [2] - 5608:4, 5648:1
airing [1] - 5641:6

al [1] - 5378:4
alert [2] - 5561:14
alerted [1] - 5388:6
alive [1] - 5516:21
allegation [1] -
5488:17
allegations [7] -
5480:14, 5481:6,
5481:23, 5574:16,
5646:5, 5648:12,
5648:16
alleged [1] - 5646:5
allegedly [1] - 5550:14
Alli [1] - 5380:17
allied [1] - 5699:4
Allied [1] - 5689:6
ALLISON [1] -
5378:19
allocated [1] -
5598:24
allotted [1] - 5407:17
allow [7] - 5395:10,
5444:13, 5496:7,
5585:22, 5586:2,
5586:10, 5650:23
allowed [2] - 5407:24,
5684:3
allowing [2] - 5525:17,
5525:18
alluded [1] - 5700:5
almost [30] - 5408:5,
5439:15, 5439:16,
5442:12, 5451:25,
5452:3, 5453:5,
5462:18, 5476:20,
5485:14, 5504:9,
5534:13, 5539:15,
5542:20, 5549:25,
5550:13, 5553:4,
5564:14, 5566:22,
5567:24, 5595:16,
5597:15, 5604:20,
5605:8, 5605:10,
5606:22, 5608:24,
5626:6, 5647:13,
5650:20
alterations [1] -
5385:1
Alzheimer's [1] -
5606:12
amazingly [1] -
5458:12
Amber [1] - 5550:1
America [1] - 5404:20
AMERICA [1] - 5378:3
amount [58] - 5410:2,
5410:13, 5411:1,
5411:23, 5412:1,
5412:2, 5412:5,
5414:4, 5424:6,

5424:13, 5424:23,
5425:4, 5425:10,
5425:12, 5425:25,
5426:6, 5427:6,
5427:7, 5427:16,
5436:18, 5437:4,
5437:5, 5480:20,
5480:22, 5484:8,
5485:2, 5485:4,
5490:16, 5491:1,
5491:8, 5506:1,
5507:16, 5507:25,
5512:13, 5516:5,
5539:14, 5549:25,
5551:23, 5552:2,
5552:4, 5585:9,
5585:13, 5589:9,
5589:17, 5590:21,
5591:8, 5595:14,
5596:17, 5598:23,
5613:11, 5613:12,
5613:18, 5628:1,
5692:13, 5693:9,
5710:4
amounts [11] -
5410:25, 5412:10,
5426:22, 5429:16,
5429:22, 5577:13,
5612:8, 5613:22,
5627:5, 5693:7
analogizing [1] -
5618:23
analogy [1] - 5402:10
analyses [9] -
5410:21, 5423:24,
5475:3, 5489:22,
5549:5, 5553:14,
5554:4, 5712:24,
5713:5
Analysis [1] - 5712:14
analysis [83] -
5399:14, 5399:18,
5400:10, 5402:9,
5408:17, 5409:20,
5410:12, 5415:21,
5416:1, 5416:6,
5417:16, 5421:12,
5422:7, 5427:23,
5430:13, 5431:7,
5434:20, 5436:17,
5443:11, 5443:15,
5446:22, 5449:4,
5451:5, 5452:24,
5457:5, 5461:18,
5462:23, 5465:6,
5467:6, 5469:17,
5469:23, 5470:3,
5471:14, 5478:19,
5483:7, 5487:12,
5488:14, 5488:21,

5510:16, 5510:19,
5546:23, 5551:23,
5552:17, 5552:24,
5553:2, 5553:12,
5553:17, 5553:22,
5554:1, 5554:10,
5554:12, 5555:12,
5555:14, 5556:9,
5557:2, 5557:4,
5557:8, 5557:12,
5557:21, 5563:25,
5571:21, 5597:4,
5601:24, 5603:3,
5614:23, 5615:7,
5616:8, 5622:14,
5624:25, 5632:3,
5632:23, 5709:21,
5710:6, 5710:12,
5711:1, 5712:4,
5712:5, 5713:6,
5713:17, 5714:14,
5714:17
analyze [15] - 5407:14,
5408:15, 5408:20,
5410:16, 5424:6,
5428:14, 5437:7,
5447:2, 5450:24,
5454:2, 5464:23,
5471:21, 5472:21,
5556:24, 5613:18
analyzed [9] -
5406:20, 5408:23,
5410:6, 5474:14,
5476:8, 5554:22,
5554:24, 5555:7,
5597:4
analyzes [1] - 5470:7
analyzing [3] -
5420:11, 5479:6,
5567:17
Andrew [1] - 5380:13
ANDREW [1] -
5378:15
anecdote [1] -
5404:24
announcement [1] -
5525:10
annual [4] - 5437:19,
5437:20, 5439:14
annually [4] - 5699:15,
5699:21, 5701:4,
5701:6
annuity [1] - 5630:16
anomalies [1] -
5624:16
anomaly [3] - 5624:6,
5624:8, 5624:10
ANSWER [10] -
5605:23, 5606:6,
5607:5, 5607:10,

5607:16, 5609:7,
5609:17, 5610:20,
5620:22, 5621:25
answer [17] - 5470:20,
5503:8, 5514:9,
5514:10, 5533:24,
5537:19, 5561:19,
5577:18, 5609:3,
5609:12, 5618:6,
5643:14, 5649:10,
5650:11, 5685:11,
5685:21, 5714:25
answering [4] -
5610:4, 5610:8,
5623:23, 5685:12
Anthony [1] - 5659:10
Anti [6] - 5412:11,
5596:10, 5612:1,
5612:5, 5612:15,
5613:1
anti [8] - 5423:24,
5443:10, 5573:6,
5573:23, 5596:12,
5611:14, 5612:8,
5614:1
Anti-Kickback [6] -
5412:11, 5596:10,
5612:1, 5612:5,
5612:15, 5613:1
anti-kickback [7] -
5423:24, 5443:10,
5573:6, 5573:23,
5611:14, 5612:8,
5614:1
antibiotic [1] - 5672:6
anticholesterol [1] -
5630:17
anticipate [4] -
5393:10, 5396:14,
5396:17, 5396:20
anticipated [1] -
5393:5
antiretroviral [12] -
5418:19, 5419:1,
5419:2, 5419:16,
5428:12, 5429:18,
5459:7, 5459:13,
5460:24, 5461:23,
5487:4, 5518:6
antiretrovirals [1] -
5555:4
anyway [2] - 5489:8,
5619:2
apologies [1] - 5391:5
apologize [7] -
5428:24, 5452:24,
5459:14, 5492:11,
5492:14, 5524:20,
5545:3
appear [2] - 5592:18,

5627:21

appearance [1] - 5380:7

appeared [1] - 5647:25

applied [1] - 5709:23

apply [6] - 5433:14, 5449:19, 5449:20, 5449:24, 5452:8, 5627:11

appreciate [7] - 5421:8, 5429:2, 5526:8, 5549:2, 5570:25, 5593:8, 5594:1

appreciates [1] - 5567:8

approach [5] - 5494:14, 5548:17, 5583:14, 5616:20, 5649:19

approaching [1] - 5456:23

appropriate [5] - 5390:1, 5509:7, 5528:14, 5615:20, 5623:15

appropriately [3] - 5642:18, 5642:22, 5679:21

approval [5] - 5386:3, 5472:13, 5472:22, 5472:25, 5694:20

approve [4] - 5680:3, 5694:1, 5695:3, 5703:1

approved [30] - 5415:8, 5415:10, 5415:13, 5472:6, 5472:14, 5481:21, 5481:24, 5482:2, 5529:4, 5674:2, 5678:24, 5679:1, 5679:7, 5679:10, 5680:2, 5681:6, 5681:13, 5684:2, 5684:4, 5685:14, 5685:19, 5685:20, 5686:5, 5689:24, 5698:17, 5699:16, 5705:5, 5717:7, 5718:19

arbitrarily [1] - 5633:7

area [3] - 5558:8, 5675:9, 5676:21

areas [3] - 5505:4, 5708:1, 5708:4

argue [4] - 5509:18, 5552:24, 5586:1, 5586:5

argued [2] - 5586:10

arguing [1] - 5586:8

argument [5] - 5393:17, 5552:15, 5618:12, 5618:13, 5650:20

argumentative [3] - 5533:25, 5537:17, 5629:3

arguments [1] - 5381:24

arm [1] - 5483:7

arms [1] - 5691:17

ARPS [1] - 5378:19

arrange [2] - 5452:2, 5718:3

arrangement [1] - 5558:10

arrive [1] - 5491:14

arrives [1] - 5622:9

articles [1] - 5408:5

ARV [13] - 5418:23, 5418:24, 5418:25, 5419:6, 5429:6, 5433:1, 5447:16, 5459:12, 5461:13, 5461:20, 5462:17

AS [3] - 5398:15, 5635:22, 5671:1

Asia [1] - 5636:18

Asia-Pacific [1] - 5636:18

asleep [1] - 5435:1

aspects [1] - 5582:1

assess [2] - 5558:20, 5720:23

assessed [3] - 5492:19, 5493:9, 5493:15

assessing [1] - 5621:8

assessment [12] - 5559:11, 5603:10, 5604:1, 5622:2, 5622:22, 5624:14, 5694:9, 5694:13, 5694:22, 5695:3, 5696:23, 5697:10

assigned [1] - 5640:24

assistant [3] - 5401:23, 5402:11, 5402:13

associate [1] - 5402:13

associated [23] - 5399:15, 5411:19, 5411:24, 5412:10, 5412:12, 5420:13, 5422:19, 5473:21, 5478:5, 5478:20,

5479:1, 5480:14, 5481:6, 5483:2, 5485:12, 5486:21, 5489:23, 5490:12, 5493:15, 5599:1, 5613:9, 5619:20

assume [16] - 5422:10, 5422:11, 5422:18, 5479:19, 5497:23, 5514:21, 5516:14, 5518:21, 5518:24, 5530:11, 5531:6, 5531:10, 5533:2, 5541:5, 5573:24

assumed [25] - 5487:22, 5488:1, 5514:18, 5514:22, 5520:13, 5520:16, 5527:18, 5528:20, 5530:25, 5531:15, 5532:10, 5533:4, 5535:20, 5537:7, 5539:8, 5540:14, 5545:10, 5545:22, 5546:3, 5546:25, 5550:11, 5560:4, 5566:14, 5569:17, 5604:6

assumes [4] - 5561:4, 5565:23, 5575:21, 5583:23

assuming [2] - 5407:1, 5538:15

assumption [21] - 5395:1, 5421:20, 5519:7, 5520:5, 5521:6, 5521:20, 5522:4, 5523:8, 5528:8, 5531:9, 5540:24, 5545:23, 5568:12, 5573:22, 5575:2, 5575:9, 5583:5, 5603:2, 5621:7, 5622:1, 5622:4

assumptions [12] - 5393:6, 5421:25, 5422:6, 5519:14, 5519:21, 5519:23, 5520:1, 5545:19, 5560:1, 5572:19, 5620:1, 5622:5

attaches [1] - 5683:20

attend [5] - 5605:19, 5689:16, 5691:12, 5706:23, 5716:20

attendance [1] - 5685:21

attended [9] -

5423:18, 5446:17, 5452:19, 5500:13, 5542:8, 5549:16, 5691:4, 5710:8, 5710:9

attendee [4] - 5453:3, 5453:4, 5453:6

attendees [12] - 5416:11, 5452:18, 5453:2, 5453:9, 5466:21, 5477:13, 5710:5, 5713:18, 5714:9, 5714:15

attendees' [2] - 5452:21, 5714:2

attending [5] - 5454:12, 5454:13, 5691:5, 5700:1, 5714:6

attention [11] - 5408:13, 5415:5, 5415:20, 5419:11, 5443:8, 5443:9, 5478:18, 5480:25, 5556:12, 5681:12, 5685:24

attest [1] - 5395:2

attested [1] - 5495:12

attesting [1] - 5427:24

attributed [8] - 5423:3, 5483:10, 5485:21, 5572:22, 5582:4, 5620:10

attuned [1] - 5659:6

audience [4] - 5416:13, 5607:9, 5608:12, 5685:13

audio [5] - 5653:18, 5656:3, 5661:12, 5661:16, 5667:15

authored [1] - 5712:14

authority [1] - 5393:21

availability [3] - 5427:11, 5427:20, 5697:13

available [7] - 5562:14, 5628:1, 5628:2, 5675:1, 5699:7, 5708:21, 5710:10

average [22] - 5425:22, 5430:8, 5430:10, 5430:21, 5430:25, 5431:3, 5431:15, 5431:16, 5432:6, 5435:9, 5435:11, 5437:19, 5438:11, 5438:15, 5446:3, 5456:12, 5460:6, 5467:10,

5474:2, 5602:21

averages [8] - 5435:7, 5435:8, 5435:10, 5435:13, 5450:5, 5450:6, 5450:17, 5453:11

avoid [3] - 5432:14, 5490:14, 5490:17

avoiding [1] - 5618:11

award [2] - 5407:24, 5482:20

awarded [1] - 5420:24

aware [21] - 5420:23, 5421:11, 5421:12, 5421:23, 5541:4, 5545:1, 5545:4, 5554:12, 5582:14, 5623:17, 5643:5, 5643:9, 5665:18, 5684:8, 5684:10, 5684:11, 5684:13, 5684:22, 5710:9, 5710:12, 5719:17

Awareness [1] - 5542:14

awareness [5] - 5542:20, 5542:23, 5543:3, 5708:14, 5714:21

B

BA [2] - 5400:17

bachelor's [4] - 5400:13, 5400:14, 5400:20

background [5] - 5408:2, 5412:16, 5426:18, 5636:21, 5697:11

backup [7] - 5543:20, 5544:4, 5544:8, 5544:11, 5544:13, 5683:1, 5683:17

bad [1] - 5578:7

balance [1] - 5678:24

balanced [1] - 5718:20

ban [1] - 5690:12

band [1] - 5693:11

bank [3] - 5406:22, 5406:24, 5406:25

bankrupt [1] - 5407:15

Bankruptcy [1] - 5405:18

bankruptcy [1] - 5407:12

banks [1] - 5407:19

bar [4] - 5438:7, 5461:10, 5468:24,

5631:10
Barbara [3] - 5566:20, 5623:22, 5623:25
bare [1] - 5721:4
bars [1] - 5447:13
Bartnett [4] - 5606:15, 5606:19, 5608:17, 5609:8
based [46] - 5421:25, 5422:19, 5422:24, 5426:24, 5436:6, 5441:21, 5466:20, 5467:5, 5467:7, 5468:13, 5496:3, 5511:15, 5511:19, 5516:15, 5519:20, 5519:23, 5534:9, 5551:22, 5556:20, 5572:19, 5577:13, 5579:4, 5579:21, 5597:20, 5615:17, 5615:18, 5630:13, 5633:24, 5633:25, 5641:8, 5651:12, 5669:16, 5678:7, 5679:9, 5680:22, 5681:8, 5683:9, 5685:22, 5686:4, 5691:11, 5693:13, 5698:4, 5700:8, 5700:10, 5710:4, 5713:16
bases [3] - 5390:21, 5390:22, 5393:20
basis [7] - 5390:25, 5420:4, 5420:7, 5551:22, 5564:19, 5616:19, 5616:25
basketball [1] - 5431:23
Beach [1] - 5636:13
bear [4] - 5598:6, 5599:21, 5603:3, 5605:1
Beard [3] - 5566:20, 5623:22, 5623:25
became [5] - 5404:15, 5478:16, 5674:10, 5674:12, 5710:9
become [7] - 5402:11, 5403:4, 5684:8, 5684:10, 5684:13, 5691:20
becomes [1] - 5520:2
BEEN [3] - 5398:14, 5635:22, 5670:25
begin [8] - 5380:23, 5397:10, 5401:18, 5417:15, 5494:15, 5558:16, 5622:24,

5635:21
beginning [13] - 5380:7, 5414:12, 5566:22, 5634:21, 5636:23, 5648:24, 5650:8, 5650:12, 5652:10, 5652:11, 5668:19, 5669:19, 5676:17
begins [7] - 5421:16, 5494:18, 5524:25, 5569:17, 5583:25, 5616:23, 5649:22
behalf [8] - 5406:1, 5406:12, 5407:14, 5407:19, 5578:19, 5578:20, 5611:13, 5704:7
behave [1] - 5710:8
behavior [31] - 5399:14, 5424:5, 5424:11, 5424:12, 5425:19, 5436:5, 5436:14, 5436:19, 5443:12, 5446:23, 5449:6, 5450:25, 5451:22, 5458:6, 5464:20, 5465:16, 5469:13, 5475:8, 5475:12, 5475:17, 5478:5, 5597:7, 5597:12, 5597:14, 5613:19, 5615:24, 5624:13, 5632:11, 5704:21, 5706:18, 5713:24
behavioral [1] - 5478:18
behind [2] - 5450:10, 5525:17
Belgium [1] - 5673:6
believes [4] - 5567:7, 5567:12, 5571:4, 5648:19
below [6] - 5486:6, 5495:10, 5688:9, 5689:18, 5697:22, 5714:8
benefited [1] - 5427:17
Berger [2] - 5593:4, 5594:7
best [8] - 5393:16, 5435:2, 5435:3, 5437:22, 5475:12, 5574:19, 5574:24, 5701:17
bet [2] - 5672:2, 5715:17
better [10] - 5415:2,

5450:19, 5450:20, 5460:11, 5488:6, 5508:14, 5602:5, 5602:20, 5640:23, 5671:18
betting [1] - 5450:19
between [62] - 5408:23, 5408:25, 5410:6, 5410:13, 5417:9, 5424:12, 5437:15, 5438:22, 5440:19, 5441:18, 5442:10, 5442:14, 5442:25, 5444:7, 5444:24, 5445:10, 5446:11, 5446:13, 5446:23, 5447:9, 5449:2, 5449:5, 5449:21, 5450:17, 5453:10, 5453:20, 5458:5, 5460:5, 5462:11, 5465:2, 5466:25, 5468:17, 5468:22, 5474:4, 5484:10, 5490:24, 5546:10, 5546:13, 5551:17, 5552:13, 5553:2, 5553:3, 5553:18, 5554:8, 5554:25, 5555:3, 5555:9, 5555:23, 5556:11, 5557:3, 5557:16, 5557:20, 5581:2, 5602:4, 5614:21, 5655:20, 5663:1, 5669:18, 5693:24, 5713:11, 5714:2, 5718:2
beyond [3] - 5561:15, 5629:14, 5630:3
bias [3] - 5432:11, 5437:22
biased [1] - 5552:4
big [11] - 5435:15, 5435:22, 5448:3, 5450:9, 5551:17, 5626:22, 5630:5, 5660:12, 5702:3, 5702:16
bigger [1] - 5714:9
biggest [1] - 5454:13
Bill [1] - 5431:15
bill [1] - 5588:9
billed [4] - 5589:22, 5590:9, 5590:14
billing [1] - 5587:15
billion [8] - 5407:25, 5414:7, 5435:21, 5450:18, 5452:11, 5453:16, 5483:21,

5484:14
billions [1] - 5407:18
BioScrip [1] - 5626:12
BioScrips [1] - 5419:25
biotech [2] - 5673:11, 5673:15
bit [25] - 5399:12, 5403:18, 5403:24, 5429:13, 5462:3, 5513:14, 5519:15, 5520:12, 5550:19, 5551:19, 5559:25, 5569:12, 5574:14, 5579:12, 5636:19, 5637:21, 5639:17, 5671:9, 5672:14, 5676:15, 5676:16, 5679:5, 5680:9, 5693:12, 5700:22
bits [1] - 5706:4
black [1] - 5475:13
block [1] - 5689:21
blocked [2] - 5526:11, 5690:8
blue [5] - 5461:10, 5484:20, 5484:21, 5484:23, 5565:18
board [5] - 5494:11, 5521:16, 5521:19, 5534:16, 5605:13
boardroom [1] - 5690:23
bodies [1] - 5615:10
body [6] - 5456:18, 5615:23, 5627:25, 5628:2, 5631:25, 5708:24
bomb [1] - 5558:22
book [7] - 5404:21, 5404:25, 5405:3, 5405:7, 5405:10, 5677:12, 5690:23
books [1] - 5404:17
Boston [11] - 5399:7, 5400:6, 5400:8, 5401:22, 5402:4, 5402:7, 5402:12, 5402:24, 5403:5, 5403:10, 5403:13
bottom [18] - 5411:24, 5430:8, 5436:12, 5438:6, 5439:13, 5439:19, 5440:15, 5457:11, 5460:10, 5467:2, 5504:20, 5528:2, 5571:24, 5612:11, 5683:15, 5692:7, 5700:7
bought [1] - 5568:17

bound [1] - 5717:13
box [3] - 5436:12, 5436:22, 5670:23
boxes [1] - 5444:25
Brad [1] - 5380:21
BRADLEY [1] - 5378:20
brainer [2] - 5433:16, 5433:17
Brancaccio [15] - 5524:9, 5527:20, 5528:2, 5529:9, 5529:13, 5529:15, 5532:11, 5532:18, 5544:4, 5604:19, 5605:2, 5605:11, 5606:14, 5606:18, 5653:6
Brancaccio's [1] - 5527:23
brand [4] - 5478:5, 5478:7, 5478:13, 5575:5
brand-new [1] - 5575:5
brands [2] - 5477:7, 5478:8
breadth [1] - 5693:1
break [18] - 5383:24, 5446:8, 5463:14, 5464:7, 5464:12, 5496:16, 5525:16, 5558:1, 5558:3, 5558:5, 5559:1, 5559:10, 5634:12, 5634:20, 5686:12, 5686:16, 5687:7, 5711:8
breakfast [1] - 5690:25
breathing [1] - 5399:10
Brian [3] - 5673:5, 5687:24, 5688:15
bribing [4] - 5642:5, 5642:8, 5642:19, 5647:17
brief [3] - 5389:7, 5391:2, 5391:9
Brief [1] - 5559:6
briefly [6] - 5384:18, 5390:25, 5391:3, 5399:23, 5445:16, 5668:10
Brimstone [1] - 5594:14
bring [8] - 5523:17, 5526:22, 5531:21, 5615:14, 5662:9, 5663:3, 5677:6,

5681:24
bringing [2] - 5563:17, 5578:17
British [1] - 5671:13
broke [1] - 5621:15
broken [2] - 5465:20, 5598:7
brought [8] - 5532:18, 5537:10, 5537:24, 5556:11, 5558:9, 5611:13, 5630:21, 5673:23
Brown [29] - 5380:17, 5384:6, 5397:2, 5494:8, 5559:18, 5593:10, 5593:15, 5597:19, 5606:1, 5606:23, 5610:9, 5621:9, 5626:20, 5630:21, 5634:10, 5635:2, 5635:17, 5652:24, 5657:15, 5659:17, 5661:13, 5666:8, 5666:24, 5668:9, 5670:9, 5670:12, 5720:15, 5721:11, 5722:15
BROWN [119] - 5378:19, 5379:4, 5379:6, 5379:7, 5380:17, 5384:12, 5397:4, 5397:14, 5421:1, 5421:5, 5421:14, 5421:19, 5422:8, 5494:9, 5494:13, 5494:17, 5494:19, 5494:21, 5495:2, 5495:5, 5495:10, 5495:14, 5495:21, 5496:10, 5496:12, 5496:14, 5497:4, 5497:8, 5497:10, 5497:11, 5498:8, 5498:9, 5499:22, 5499:25, 5507:1, 5507:4, 5507:5, 5517:3, 5517:8, 5521:16, 5521:18, 5526:20, 5526:24, 5527:3, 5527:5, 5537:23, 5547:14, 5547:16, 5547:19, 5547:22, 5547:24, 5548:17, 5548:22, 5557:24, 5558:2, 5559:19, 5559:21, 5571:10, 5571:12, 5574:9, 5574:10, 5584:2, 5584:5, 5584:10,

5584:13, 5584:17, 5584:19, 5585:14, 5586:12, 5586:16, 5586:18, 5593:7, 5593:14, 5593:17, 5593:19, 5613:3, 5616:18, 5616:20, 5617:1, 5617:5, 5617:10, 5618:6, 5629:2, 5634:14, 5635:3, 5635:5, 5635:9, 5635:12, 5635:18, 5636:3, 5636:4, 5638:15, 5638:19, 5639:19, 5639:22, 5643:2, 5643:3, 5650:8, 5650:12, 5650:14, 5650:22, 5651:15, 5651:17, 5668:10, 5668:12, 5668:16, 5668:18, 5668:25, 5669:1, 5670:8, 5670:13, 5670:17, 5720:5, 5720:16, 5721:14, 5721:22, 5722:6, 5722:10, 5722:16
BU [2] - 5401:24, 5401:25
buckets [1] - 5439:4
build [1] - 5679:12
building [7] - 5524:23, 5525:4, 5525:5, 5525:19, 5525:25, 5526:3, 5603:10
Building [1] - 5378:8
bulk [1] - 5587:19
bullet [11] - 5678:19, 5681:5, 5685:7, 5685:8, 5697:8, 5699:12, 5699:14, 5700:7, 5713:22, 5714:5, 5714:8
bullets [1] - 5706:9
bunch [2] - 5702:3, 5707:4
burdens [1] - 5674:20
Bureau [11] - 5424:15, 5424:20, 5430:9, 5436:23, 5459:2, 5460:6, 5596:4, 5677:12, 5677:22, 5699:2, 5706:2
bureau [40] - 5429:16, 5437:5, 5444:4, 5467:12, 5468:8, 5477:14, 5479:2, 5480:2, 5490:11, 5522:18, 5574:4,

5590:22, 5591:5, 5597:9, 5674:11, 5676:16, 5676:18, 5676:23, 5676:24, 5681:8, 5683:1, 5684:23, 5688:16, 5689:8, 5691:25, 5692:14, 5694:12, 5695:24, 5697:19, 5698:15, 5700:3, 5700:12, 5700:18, 5701:6, 5703:10, 5703:21, 5705:3, 5709:4, 5709:5, 5711:6
bureaus [1] - 5409:22
business [15] - 5399:24, 5400:4, 5400:25, 5401:4, 5403:23, 5404:6, 5591:13, 5602:17, 5612:16, 5641:20, 5656:20, 5671:16, 5690:22, 5704:15, 5718:1
Business [2] - 5400:2, 5401:21
busy [1] - 5384:19
buy [2] - 5406:9, 5436:2
buying [3] - 5404:1, 5450:19, 5450:20
Buyout [1] - 5405:11
buyouts [1] - 5404:1
BY [74] - 5378:14, 5378:19, 5379:4, 5379:4, 5379:5, 5379:6, 5379:6, 5379:7, 5379:8, 5398:25, 5421:9, 5422:16, 5464:11, 5497:11, 5498:9, 5499:25, 5507:5, 5517:8, 5521:18, 5527:5, 5537:23, 5547:24, 5548:22, 5559:21, 5571:12, 5574:10, 5586:18, 5594:3, 5597:1, 5611:23, 5612:12, 5613:6, 5619:12, 5620:15, 5628:11, 5629:7, 5636:4, 5638:19, 5639:22, 5643:3, 5651:17, 5653:2, 5661:17, 5667:16, 5668:12, 5668:18, 5669:1, 5671:5, 5677:8, 5677:20, 5678:16,

5682:1, 5682:20, 5685:6, 5687:6, 5687:14, 5688:8, 5692:8, 5695:18, 5696:7, 5699:11, 5702:7, 5704:4, 5705:10, 5706:1, 5706:7, 5710:22, 5712:11, 5712:23, 5713:4, 5715:21, 5716:12, 5717:21

C

cabinet [1] - 5662:17
calculate [11] - 5427:15, 5432:5, 5472:2, 5486:21, 5493:18, 5494:1, 5542:4, 5561:3, 5596:17, 5614:22, 5630:3
calculated [9] - 5415:21, 5421:13, 5421:21, 5422:24, 5490:7, 5492:24, 5493:24, 5598:25, 5612:21
calculating [3] - 5426:18, 5612:2, 5613:8
calculation [16] - 5409:10, 5410:17, 5422:18, 5431:1, 5478:20, 5479:18, 5488:22, 5489:2, 5533:19, 5556:17, 5556:20, 5613:21, 5614:17, 5628:17, 5629:9, 5697:3
calculations [6] - 5422:17, 5423:20, 5489:23, 5555:21, 5562:1, 5604:12
calculator [1] - 5452:12
calendar [4] - 5664:10, 5664:16, 5664:20, 5664:21
calibration [1] - 5661:2
camera [4] - 5381:17, 5383:13, 5383:20, 5720:21
Canada [3] - 5671:13, 5671:17, 5709:9
Canadian [1] - 5671:12
Candice [1] - 5721:14
cannot [20] - 5406:10,

5435:17, 5440:23, 5444:23, 5446:2, 5458:16, 5501:5, 5501:6, 5510:10, 5510:15, 5516:25, 5523:2, 5523:22, 5523:23, 5543:7, 5582:10, 5592:25, 5597:13, 5602:1, 5683:13
capability [1] - 5692:2
capacity [1] - 5641:22
capital [1] - 5400:9
capture [2] - 5423:6, 5423:7
cardiology [1] - 5707:25
care [26] - 5476:25, 5478:1, 5517:24, 5574:18, 5581:2, 5637:4, 5672:4, 5674:5, 5676:22, 5677:2, 5679:16, 5681:20, 5684:18, 5684:19, 5685:10, 5692:23, 5693:25, 5694:17, 5695:4, 5695:7, 5695:9, 5698:10, 5699:4, 5699:5, 5704:19
careers [1] - 5637:3
careful [2] - 5534:12, 5617:22
caring [1] - 5674:5
Carolina [1] - 5431:25
case [102] - 5384:7, 5386:18, 5387:17, 5389:7, 5389:13, 5389:14, 5389:21, 5390:9, 5393:7, 5396:8, 5398:2, 5398:4, 5398:6, 5408:4, 5408:14, 5420:25, 5433:5, 5442:2, 5444:19, 5446:6, 5446:9, 5457:17, 5462:22, 5464:15, 5465:14, 5468:5, 5469:9, 5470:2, 5473:2, 5475:20, 5480:14, 5481:3, 5485:15, 5500:3, 5501:14, 5517:9, 5517:13, 5518:1, 5520:11, 5520:13, 5522:11, 5522:15, 5525:13, 5527:15, 5528:8, 5529:25, 5531:5, 5531:7, 5533:1,

5533:7, 5533:16, 5535:3, 5535:13, 5537:5, 5538:4, 5539:15, 5540:11, 5541:6, 5543:1, 5544:8, 5545:2, 5545:20, 5547:10, 5565:7, 5570:23, 5578:9, 5579:1, 5582:1, 5589:3, 5589:6, 5589:19, 5590:3, 5590:5, 5590:15, 5591:23, 5592:6, 5592:8, 5592:19, 5592:24, 5593:1, 5593:4, 5594:17, 5595:8, 5595:22, 5615:21, 5616:16, 5618:13, 5618:14, 5618:17, 5618:19, 5618:23, 5624:12, 5626:14, 5629:17, 5629:21, 5630:7, 5631:15, 5634:1, 5637:8, 5643:4, 5665:8, 5721:18

cases [14] - 5407:7, 5446:2, 5485:23, 5568:19, 5578:1, 5578:5, 5578:6, 5592:21, 5592:22, 5593:1, 5613:15, 5617:8, 5620:19, 5681:23

cash [2] - 5613:13, 5613:14

categories [3] - 5505:14, 5550:8, 5553:7

categorized [1] - 5439:4

causal [2] - 5546:12, 5546:18

causation [5] - 5616:17, 5617:7, 5617:9, 5617:17, 5618:16

caused [1] - 5508:8

caveat [2] - 5388:13, 5398:5

certain [17] - 5422:18, 5458:15, 5458:16, 5458:17, 5486:12, 5515:9, 5519:20, 5531:4, 5532:19, 5534:11, 5564:15, 5586:25, 5607:6, 5666:13, 5667:21, 5708:22

certainly [3] - 5384:2, 5593:3, 5675:6

certainty [10] - 5458:17, 5458:18, 5492:19, 5492:25, 5493:10, 5493:19, 5494:2, 5616:9, 5622:3, 5628:4

CERTIFICATE [1] - 5723:1

certify [1] - 5723:4

Cesario [3] - 5660:6, 5660:8, 5660:24

cetera [2] - 5697:14, 5698:11

chain [1] - 5688:9

challenge [4] - 5399:11, 5405:15, 5561:18, 5632:6

challenged [1] - 5632:7

challenges [1] - 5666:22

challenging [1] - 5674:23

champion [1] - 5455:20

chance [22] - 5434:22, 5435:20, 5435:23, 5435:24, 5435:25, 5436:1, 5440:11, 5442:24, 5443:1, 5450:1, 5450:17, 5452:16, 5452:17, 5453:9, 5453:15, 5458:18, 5507:8, 5557:23, 5569:4, 5607:18, 5653:15

change [12] - 5443:8, 5495:7, 5570:6, 5570:12, 5570:17, 5579:4, 5621:10, 5622:6, 5645:16, 5665:13, 5675:18

changed [2] - 5644:19, 5666:8

changes [2] - 5558:14, 5572:5

characteristic [1] - 5435:12

characteristics [1] - 5555:9

characterization [1] - 5631:7

charge [11] - 5406:23, 5406:25, 5586:5, 5588:18, 5588:19, 5588:20, 5588:21, 5588:23, 5591:13, 5591:15, 5592:25

charging [3] - 5587:11, 5587:25, 5589:18

charity [1] - 5469:25

chart [7] - 5461:11, 5468:24, 5542:19, 5548:3, 5580:1, 5602:2, 5631:10

charts [1] - 5438:7

chat [2] - 5396:25, 5720:1

cheap [2] - 5594:12, 5594:14

check [5] - 5425:5, 5516:14, 5597:25, 5691:4, 5691:5

checked [5] - 5434:8, 5435:23, 5489:7, 5552:15, 5556:2

checks [2] - 5424:18

Chemicals [2] - 5401:8, 5401:14

cherry [7] - 5531:24, 5532:1, 5532:4, 5597:3, 5597:16, 5601:25

cherry-pick [4] - 5531:24, 5597:3, 5597:16

cherry-picking [3] - 5532:1, 5532:4, 5601:25

cholesterol [1] - 5512:16

choose [2] - 5387:23, 5574:23

chose [1] - 5604:16

Chris [5] - 5688:10, 5688:23, 5689:1, 5689:3, 5689:15

Christina [1] - 5605:11

Christine [2] - 5605:2, 5653:6

chronology [1] - 5675:12

cigarette [1] - 5616:16

circle [4] - 5482:6, 5484:6, 5484:23, 5513:1

circumstance [2] - 5387:15, 5517:22

cited [2] - 5504:19, 5507:13

cites [1] - 5393:19

CIVIL [1] - 5378:3

claim [17] - 5412:11, 5417:20, 5418:15, 5435:18, 5443:10, 5487:18, 5487:19,

5513:5, 5513:6, 5513:21, 5514:12, 5516:11, 5544:15, 5556:14, 5560:22, 5578:1

claimed [1] - 5541:14

claims [56] - 5409:15, 5409:16, 5419:12, 5419:13, 5427:4, 5427:21, 5480:12, 5480:13, 5480:16, 5481:1, 5485:12, 5485:14, 5485:15, 5485:16, 5485:18, 5486:5, 5486:11, 5488:11, 5491:18, 5492:3, 5492:8, 5492:13, 5492:14, 5492:17, 5492:18, 5493:1, 5493:14, 5493:15, 5493:18, 5498:25, 5499:1, 5512:12, 5513:2, 5513:16, 5514:1, 5514:3, 5514:18, 5514:22, 5515:2, 5515:4, 5515:6, 5515:9, 5515:24, 5517:12, 5535:13, 5544:4, 5549:25, 5576:5, 5576:6, 5611:15, 5612:21, 5628:1, 5628:6

Claims [7] - 5412:12, 5578:6, 5578:9, 5612:1, 5612:6, 5612:16, 5665:23

clarification [1] - 5383:12

clarifications [1] - 5703:2

clarify [3] - 5390:20, 5585:21, 5651:8

Clarkson [1] - 5378:8

class [1] - 5518:7

classes [3] - 5400:11, 5400:24, 5708:21

classically [1] - 5441:3

classroom [1] - 5624:10

clean [3] - 5489:8, 5586:3, 5625:19

clear [17] - 5387:22, 5389:20, 5423:16, 5427:5, 5427:21, 5449:13, 5449:15, 5468:16, 5475:15, 5558:5, 5559:11, 5594:21, 5609:1,

5618:10, 5679:23, 5682:23, 5688:15

cleared [1] - 5558:17

clearly [5] - 5438:7, 5442:24, 5476:1, 5519:4, 5685:22

CLERK [17] - 5380:4, 5397:16, 5397:23, 5398:16, 5464:1, 5559:3, 5559:5, 5559:7, 5634:23, 5635:1, 5635:14, 5635:24, 5671:2, 5686:18, 5686:20, 5686:24, 5719:20

client [2] - 5588:23, 5667:11

clinical [7] - 5679:17, 5679:20, 5692:23, 5693:4, 5700:8, 5704:22, 5718:17

clinically [1] - 5620:2

clinics [2] - 5568:17, 5568:21

clip [12] - 5572:14, 5638:15, 5638:18, 5638:20, 5639:19, 5639:21, 5661:10, 5661:12, 5667:14, 5668:16, 5668:17

clips [1] - 5638:11

close [7] - 5587:15, 5587:22, 5589:10, 5589:18, 5628:8, 5719:12, 5721:25

closing [2] - 5586:6, 5633:24

clue [1] - 5589:21

CMS [14] - 5497:15, 5497:20, 5498:1, 5500:21, 5501:2, 5501:15, 5513:17, 5514:13, 5515:14, 5545:4, 5577:15, 5577:16, 5610:25, 5611:4

coaching [1] - 5637:19

Coast [2] - 5671:17, 5672:25

coauthored [1] - 5404:21

cocktails [1] - 5674:25

code [1] - 5631:18

codes [1] - 5489:16

coding [1] - 5516:15

coffee [1] - 5673:3

coincided [1] - 5678:3

collapsed [1] - 5407:15

colleague [2] - 5404:22, 5534:1
colleagues [3] - 5594:16, 5702:4
collect [3] - 5518:17, 5627:16, 5711:18
collection [2] - 5587:15, 5588:3
college [2] - 5400:14, 5400:22
color [1] - 5425:17
colorful [1] - 5404:19
colors [1] - 5447:13
Columbia [1] - 5671:13
column [1] - 5549:21
columns [1] - 5702:17
combined [1] - 5589:25
comfortable [11] - 5640:10, 5641:4, 5641:6, 5641:13, 5648:1, 5662:20, 5666:25, 5667:2, 5667:19, 5668:13, 5668:20
coming [9] - 5388:14, 5396:15, 5471:6, 5525:7, 5544:1, 5608:4, 5617:12, 5640:10, 5646:14
command [1] - 5693:16
Commencing [1] - 5378:10
comments [3] - 5680:19, 5680:22, 5681:2
Committee [2] - 5406:1, 5679:13
committee [10] - 5679:16, 5695:5, 5695:8, 5695:9, 5698:10, 5699:17, 5700:13, 5702:25, 5717:8
communicate [2] - 5685:13, 5690:2
communicated [1] - 5413:10
communicating [1] - 5436:11
communication [2] - 5657:14, 5682:23
communications [1] - 5689:19
community [9] - 5599:11, 5697:12, 5699:3, 5708:14, 5709:2, 5709:4,

5709:5, 5709:6, 5709:7
companies [21] - 5401:14, 5404:1, 5404:2, 5404:4, 5404:9, 5404:13, 5404:22, 5405:6, 5406:13, 5407:4, 5407:21, 5582:15, 5586:20, 5595:15, 5595:16, 5596:8, 5611:6, 5616:16, 5691:19, 5692:1, 5707:14
Company [1] - 5718:12
company [68] - 5401:15, 5401:16, 5401:18, 5403:19, 5403:21, 5404:5, 5406:9, 5421:2, 5469:18, 5469:22, 5469:24, 5472:13, 5474:3, 5477:19, 5477:21, 5478:9, 5545:6, 5574:23, 5582:18, 5587:14, 5606:5, 5606:7, 5606:9, 5610:13, 5661:3, 5669:16, 5669:23, 5670:2, 5672:11, 5673:1, 5673:7, 5673:12, 5673:15, 5676:1, 5678:8, 5678:25, 5679:1, 5679:7, 5680:14, 5681:6, 5681:14, 5684:2, 5684:7, 5684:16, 5685:8, 5689:2, 5690:11, 5690:20, 5691:12, 5692:18, 5697:24, 5698:3, 5704:6, 5704:7, 5704:9, 5705:2, 5707:13, 5711:4, 5711:9, 5711:17, 5711:22, 5714:14, 5714:18, 5716:13, 5717:23, 5718:2, 5718:4, 5718:15
company's [1] - 5478:6
company-approved [1] - 5684:2
compare [6] - 5410:13, 5433:12, 5435:13, 5437:4, 5445:14, 5460:22
compared [7] -

5414:13, 5425:11, 5430:14, 5433:22, 5435:19, 5459:16, 5504:4
comparing [2] - 5444:13, 5553:22
comparison [3] - 5443:16, 5461:8, 5631:8
comparisons [1] - 5631:1
compensated [2] - 5578:22, 5579:7
Compensation [1] - 5692:10
compensation [35] - 5408:20, 5408:24, 5409:21, 5423:24, 5425:11, 5425:15, 5428:16, 5436:18, 5436:24, 5436:25, 5437:25, 5438:6, 5438:22, 5438:25, 5439:1, 5439:4, 5439:8, 5439:9, 5440:5, 5440:15, 5440:19, 5441:21, 5442:3, 5442:15, 5442:25, 5443:10, 5454:3, 5591:9, 5632:12, 5636:17, 5661:2, 5692:9, 5717:24
competing [1] - 5433:3
competitor [2] - 5414:22, 5414:25
competitor's [1] - 5415:1
competitors [2] - 5414:14, 5415:3
compile [2] - 5701:17, 5702:24
compiling [1] - 5702:16
complaint [1] - 5642:18
complaints [5] - 5637:19, 5640:11, 5640:13, 5642:7, 5658:11
complete [4] - 5387:9, 5388:3, 5394:2, 5634:2
Complete [1] - 5405:10
completely [1] - 5389:20
Compliance [2] - 5706:8, 5718:11

compliance [24] - 5381:9, 5642:15, 5646:5, 5648:16, 5679:16, 5681:20, 5684:18, 5684:19, 5689:9, 5691:18, 5692:24, 5693:25, 5694:17, 5695:4, 5695:7, 5695:10, 5698:10, 5704:19, 5706:9, 5706:10, 5706:15, 5716:21, 5717:14, 5721:5
comply [2] - 5700:13, 5718:25
component [2] - 5705:3, 5706:15
comport [1] - 5567:25
comprehend [1] - 5506:21
comprehensive [1] - 5694:12
comprised [2] - 5459:20, 5695:9
computer [3] - 5378:25, 5525:25, 5625:14
computer-aided [1] - 5378:25
computers [1] - 5411:3
concept [4] - 5574:17, 5619:20, 5620:6, 5621:14
concern [3] - 5389:19, 5540:12, 5561:16
concerned [5] - 5525:20, 5565:7, 5565:9, 5566:17, 5606:11
concerns [16] - 5618:11, 5637:19, 5639:24, 5640:10, 5641:1, 5641:6, 5642:8, 5646:5, 5648:1, 5659:10, 5659:18, 5660:8, 5660:9, 5661:4, 5667:8, 5668:6
conclude [3] - 5428:3, 5475:7, 5559:24
concluded [11] - 5422:14, 5436:6, 5475:3, 5475:11, 5475:16, 5497:6, 5527:1, 5566:23, 5586:14, 5619:5, 5651:13
conclusion [8] - 5389:13, 5389:14,

5436:12, 5475:21, 5475:22, 5477:11, 5556:15, 5556:25
condition [6] - 5509:22, 5510:4, 5510:11, 5511:12, 5708:22, 5708:23
conduct [6] - 5470:11, 5694:14, 5694:24, 5704:6, 5704:7, 5717:1
conducted [5] - 5684:12, 5689:4, 5691:6, 5710:6, 5713:6
conducting [4] - 5690:21, 5693:15, 5699:23, 5714:20
conference [2] - 5671:22, 5673:3
confirm [1] - 5632:9
confirmed [1] - 5632:11
conflict [1] - 5640:7
confused [1] - 5635:11
Congress [6] - 5405:24, 5406:4, 5406:7, 5406:8, 5406:12
connect [1] - 5617:18
connecting [3] - 5617:23, 5663:1, 5664:6
connection [4] - 5517:9, 5524:10, 5617:24, 5694:22
conservative [10] - 5489:1, 5489:6, 5581:15, 5583:4, 5583:7, 5583:13, 5624:14, 5624:20, 5627:12, 5630:15
conservatively [3] - 5486:12, 5487:15, 5488:1
consider [18] - 5416:21, 5418:16, 5421:6, 5502:5, 5511:11, 5551:13, 5569:18, 5571:15, 5573:2, 5573:3, 5585:17, 5587:6, 5591:9, 5591:16, 5591:21, 5591:25, 5592:8, 5707:22
consideration [2] - 5591:12, 5634:2
considered [14] - 5416:9, 5418:5,

5580:17, 5580:24, 5581:7, 5581:8, 5581:14, 5582:21, 5582:24, 5587:3, 5587:8, 5587:9, 5588:5, 5590:18, 5591:19, 5592:10, 5592:16, 5594:19, 5597:24, 5598:18, 5600:1, 5600:4, 5600:10, 5600:14, 5600:15, 5600:25, 5601:2, 5601:9, 5601:10, 5601:13, 5601:17, 5602:24, 5605:2, 5605:5, 5607:22, 5611:9, 5611:10, 5613:11, 5613:21, 5620:4, 5625:12, 5625:25, 5626:24, 5637:12, 5638:22, 5639:15, 5644:5, 5644:10, 5644:14, 5645:15, 5646:13, 5646:20, 5646:22, 5646:23, 5650:5, 5653:8, 5653:14, 5653:17, 5654:9, 5654:11, 5654:12, 5654:17, 5654:21, 5654:22, 5654:24, 5656:18, 5656:21, 5656:22, 5656:24, 5657:19, 5658:12, 5658:13, 5658:19, 5659:23, 5660:22, 5661:8, 5662:25, 5665:2, 5665:9, 5665:20, 5666:12, 5668:6, 5669:5, 5669:11, 5669:17, 5669:20, 5669:24, 5670:7, 5676:7, 5677:24, 5682:13, 5685:18, 5690:13, 5693:8, 5698:12, 5708:11, 5708:12, 5711:10, 5711:14, 5714:16, 5723:4

corrected [1] - 5650:21

correcting [1] - 5459:14

correction [4] - 5417:24, 5489:25, 5644:12, 5645:5

correctly [2] - 5506:18, 5641:19

correlate [3] -

5489:17, 5575:3, 5713:23

correlated [4] - 5441:23, 5442:5, 5443:2, 5632:12

correlation [16] - 5440:13, 5441:12, 5441:20, 5442:14, 5442:25, 5443:4, 5458:2, 5458:3, 5458:12, 5602:3, 5616:17, 5617:2, 5617:7, 5617:8, 5617:16

Correlation [1] - 5440:24

correlation/ causation [1] - 5618:12

corroborate [1] - 5464:24

corroborated [2] - 5470:3, 5518:25

corroborates [1] - 5465:6

cost [4] - 5406:10, 5611:24, 5612:4, 5612:13

costs [1] - 5472:1

couch [1] - 5388:5

counsel [28] - 5380:7, 5390:8, 5413:10, 5418:12, 5422:1, 5454:15, 5499:23, 5558:9, 5574:2, 5584:23, 5584:25, 5602:1, 5609:19, 5616:13, 5621:12, 5630:14, 5649:6, 5653:13, 5677:7, 5681:25, 5687:13, 5705:9, 5712:9, 5715:20, 5719:16, 5719:19, 5720:9, 5721:6

counsel's [2] - 5421:22, 5646:12

count [7] - 5489:4, 5490:15, 5539:18, 5569:22, 5572:16, 5623:8, 5696:6

counted [2] - 5539:21, 5539:22

counterproposal [1] - 5385:7

counting [2] - 5490:15, 5490:17

country [5] - 5516:19, 5538:7, 5607:4, 5671:21, 5707:4

couple [16] - 5409:6, 5513:15, 5564:8, 5564:10, 5590:10, 5599:3, 5606:4, 5638:11, 5640:13, 5651:18, 5671:19, 5671:22, 5682:5, 5690:16, 5695:15, 5710:17

course [25] - 5383:21, 5403:1, 5416:14, 5468:1, 5478:16, 5480:5, 5481:1, 5481:3, 5504:12, 5522:13, 5549:1, 5551:16, 5593:14, 5593:17, 5621:6, 5631:3, 5644:1, 5644:7, 5655:19, 5658:1, 5680:22, 5685:9, 5707:1, 5711:17, 5711:22

court [24] - 5380:1, 5383:7, 5413:17, 5422:15, 5469:9, 5497:7, 5523:15, 5524:14, 5527:2, 5527:7, 5531:17, 5532:18, 5534:15, 5552:17, 5557:23, 5586:15, 5619:6, 5634:17, 5645:18, 5646:10, 5651:14, 5652:9, 5653:19, 5653:23

COURT [225] - 5378:1, 5380:4, 5380:5, 5380:16, 5380:22, 5381:8, 5381:11, 5381:16, 5382:7, 5382:9, 5382:18, 5382:20, 5382:25, 5383:3, 5383:15, 5383:19, 5383:22, 5384:3, 5384:13, 5384:25, 5385:3, 5385:15, 5385:19, 5385:21, 5385:23, 5386:1, 5386:6, 5386:8, 5386:11, 5387:4, 5387:7, 5387:19, 5387:21, 5388:5, 5388:13, 5388:16, 5388:22, 5389:2, 5389:18, 5390:17, 5390:24, 5391:14, 5392:2, 5392:7, 5392:10, 5392:22, 5393:3, 5393:12, 5393:24, 5394:2, 5394:8,

5394:12, 5395:8, 5395:24, 5396:2, 5396:14, 5396:19, 5396:24, 5397:2, 5397:5, 5397:16, 5397:17, 5397:20, 5397:23, 5397:24, 5398:13, 5398:16, 5398:19, 5398:22, 5421:3, 5421:6, 5421:15, 5421:17, 5421:24, 5422:13, 5463:13, 5463:16, 5463:21, 5463:24, 5464:1, 5464:3, 5464:9, 5494:7, 5494:12, 5494:16, 5494:20, 5495:1, 5495:4, 5495:9, 5495:13, 5495:18, 5496:6, 5496:20, 5496:25, 5497:9, 5499:24, 5506:23, 5507:3, 5517:6, 5524:24, 5525:3, 5525:14, 5526:8, 5526:11, 5526:13, 5526:18, 5526:21, 5526:25, 5527:4, 5537:14, 5537:16, 5537:19, 5547:20, 5547:23, 5548:18, 5558:1, 5558:3, 5559:3, 5559:5, 5559:7, 5559:9, 5583:24, 5584:1, 5584:4, 5584:7, 5584:11, 5584:15, 5584:18, 5585:2, 5585:20, 5586:2, 5586:9, 5586:17, 5593:10, 5593:15, 5593:21, 5593:24, 5613:4, 5616:19, 5616:22, 5616:24, 5617:4, 5617:12, 5617:15, 5617:18, 5617:22, 5618:1, 5618:5, 5618:8, 5618:17, 5618:21, 5618:23, 5619:1, 5619:4, 5619:7, 5629:4, 5633:17, 5633:21, 5634:1, 5634:6, 5634:8, 5634:10, 5634:19, 5634:23, 5635:1, 5635:2, 5635:4, 5635:7, 5635:10, 5635:13, 5635:14, 5635:16, 5635:20,

5635:24, 5636:2, 5638:17, 5649:21, 5650:3, 5650:6, 5650:11, 5650:13, 5650:19, 5650:23, 5651:1, 5651:4, 5651:10, 5651:16, 5652:24, 5668:8, 5668:11, 5670:9, 5670:12, 5670:16, 5670:20, 5671:2, 5677:16, 5682:17, 5686:8, 5686:11, 5686:15, 5686:18, 5686:20, 5686:21, 5686:23, 5686:24, 5687:1, 5688:6, 5705:22, 5712:21, 5716:10, 5719:5, 5719:8, 5719:11, 5719:20, 5719:22, 5720:6, 5720:15, 5720:17, 5721:19, 5721:23, 5722:7, 5722:11, 5722:14, 5722:17, 5723:1

Court [7] - 5378:23, 5381:14, 5382:16, 5390:8, 5421:21, 5722:18, 5723:12

Court's [5] - 5382:13, 5389:17, 5390:13, 5494:10, 5521:17

courthouse [6] - 5558:7, 5558:11, 5558:20, 5558:25, 5559:2, 5559:12

Courthouse [1] - 5378:8

courtroom [14] - 5397:22, 5463:19, 5464:2, 5512:5, 5521:14, 5524:7, 5559:8, 5571:3, 5583:17, 5609:4, 5619:25, 5634:24, 5635:15, 5686:25

cover [9] - 5404:19, 5553:6, 5607:18, 5607:20, 5611:24, 5612:4, 5612:13, 5701:23, 5704:18

covered [1] - 5718:18

create [2] - 5679:9, 5694:14

created [1] - 5517:25

credentials [1] - 5399:23

credible [2] - 5475:25, 5563:23

criteria [13] - 5486:24, 5487:5, 5534:9, 5692:21, 5696:12, 5696:14, 5697:19, 5698:14, 5700:5, 5700:11, 5702:15, 5703:3, 5703:19
critical [1] - 5570:14
critique [1] - 5462:23
critiqued [1] - 5554:1
cross [6] - 5445:4, 5495:22, 5496:8, 5609:20, 5650:24, 5651:11
CROSS [4] - 5379:4, 5379:6, 5497:11, 5653:2
cross-examination [1] - 5651:11
CROSS-EXAMINATION [4] - 5379:4, 5379:6, 5497:11, 5653:2
cross-examine [1] - 5650:24
cross-examined [1] - 5445:4
crossover [1] - 5478:12
CRR [1] - 5723:11
Cruz [1] - 5688:10
curious [1] - 5561:25
current [3] - 5470:22, 5636:16, 5641:2
cursory [2] - 5381:1, 5383:9
customer [1] - 5680:16
customers [1] - 5673:5
cut [3] - 5506:18, 5629:13, 5633:2
cutting [2] - 5392:24, 5720:10
CVS [1] - 5626:10

D

D-3005 [2] - 5517:3, 5517:7
D-4006 [6] - 5677:6, 5677:14, 5677:17, 5685:5, 5696:5, 5712:10
D-4019 [1] - 5682:15
D-4066 [3] - 5712:10, 5712:19, 5712:22
D-4123 [1] - 5686:7
D-4131 [1] - 5705:23
D-4187 [1] - 5716:11

D-9103 [1] - 5547:13
D.C [1] - 5636:25
daily [9] - 5415:11, 5419:18, 5419:21, 5420:7, 5481:22, 5481:24, 5488:25, 5490:13, 5626:13
Dallas [1] - 5378:17
damage [2] - 5598:25, 5629:14
damages [114] - 5394:24, 5399:18, 5409:9, 5411:23, 5415:22, 5420:11, 5420:13, 5420:14, 5420:21, 5420:24, 5421:21, 5422:23, 5423:5, 5423:14, 5423:20, 5424:6, 5424:9, 5426:18, 5478:20, 5479:18, 5479:22, 5480:22, 5482:19, 5483:1, 5483:10, 5485:13, 5486:6, 5486:12, 5486:21, 5487:20, 5489:4, 5489:10, 5490:7, 5490:8, 5490:25, 5491:6, 5491:8, 5491:9, 5491:13, 5491:15, 5492:23, 5492:24, 5493:1, 5493:2, 5493:3, 5493:4, 5493:7, 5493:16, 5493:22, 5493:23, 5495:2, 5495:4, 5496:3, 5497:25, 5498:13, 5502:8, 5502:15, 5503:3, 5512:10, 5512:13, 5513:1, 5515:2, 5519:20, 5534:5, 5540:14, 5540:19, 5541:14, 5542:4, 5547:1, 5560:6, 5565:23, 5569:16, 5573:3, 5575:20, 5575:23, 5576:17, 5577:14, 5582:22, 5583:20, 5584:2, 5585:7, 5585:10, 5585:12, 5586:7, 5587:1, 5597:20, 5598:21, 5598:24, 5599:7, 5599:8, 5603:13, 5603:14, 5603:25, 5604:12, 5612:2, 5612:7, 5612:21, 5613:9,

5613:21, 5613:22, 5614:17, 5615:7, 5619:16, 5621:8, 5622:2, 5623:2, 5624:14, 5627:14, 5630:3
data [71] - 5408:23, 5410:13, 5410:18, 5410:21, 5410:22, 5411:2, 5411:7, 5411:10, 5411:11, 5411:18, 5411:19, 5417:3, 5418:20, 5419:19, 5420:1, 5426:25, 5427:9, 5427:11, 5427:13, 5427:20, 5428:14, 5430:7, 5437:7, 5448:5, 5449:10, 5449:11, 5450:15, 5452:7, 5456:18, 5479:25, 5503:23, 5504:19, 5504:21, 5506:5, 5514:6, 5547:6, 5550:13, 5552:22, 5560:16, 5562:8, 5565:12, 5567:18, 5567:25, 5569:3, 5572:1, 5575:14, 5579:21, 5580:14, 5580:15, 5580:23, 5581:5, 5604:2, 5604:11, 5615:11, 5624:6, 5624:21, 5625:8, 5625:10, 5625:11, 5625:22, 5626:16, 5627:25, 5628:2, 5633:2, 5633:3, 5711:18, 5711:23, 5711:24, 5712:4
database [9] - 5417:9, 5418:23, 5419:22, 5427:4, 5434:9, 5466:21, 5516:15, 5538:14, 5562:22
databases [1] - 5482:12
datasets [2] - 5410:16, 5445:17
date [8] - 5387:10, 5387:24, 5388:8, 5391:9, 5398:6, 5561:12, 5573:13, 5573:15
Date [1] - 5723:12
dates [1] - 5562:25
day-to-day [1] - 5637:16
days [5] - 5386:19,

5390:9, 5419:4, 5419:8, 5623:7
DDMAC [8] - 5394:20, 5680:9, 5680:11, 5680:12, 5680:14, 5680:16, 5680:19, 5681:1
de [6] - 5490:16, 5490:17, 5491:11, 5492:2, 5495:11, 5495:23
de-duplicated [1] - 5491:11
de-duplication [5] - 5490:16, 5490:17, 5492:2, 5495:11, 5495:23
deal [10] - 5388:23, 5435:15, 5450:9, 5495:19, 5495:21, 5496:7, 5581:25, 5624:11, 5624:12
dealing [4] - 5386:14, 5655:7, 5659:4, 5663:18
deals [1] - 5658:10
Dear [1] - 5682:21
debt [1] - 5407:18
decade [1] - 5564:21
decades [1] - 5693:15
December [6] - 5480:8, 5480:10, 5499:10, 5560:24, 5561:11, 5562:1
decide [4] - 5393:9, 5489:2, 5515:14, 5586:9
decided [10] - 5427:8, 5437:12, 5487:15, 5488:4, 5488:18, 5595:1, 5625:7, 5625:15, 5644:18, 5648:8
deciding [3] - 5551:13, 5570:20, 5571:5
decision [10] - 5391:9, 5512:9, 5550:20, 5693:22, 5693:23, 5700:11, 5703:9, 5703:14, 5703:15, 5703:20
decision-making [3] - 5703:9, 5703:15, 5703:20
decisions [1] - 5551:7
deck [17] - 5679:9, 5679:12, 5679:15, 5679:19, 5680:2, 5684:4, 5684:5,

5685:20, 5689:24, 5704:23, 5705:6, 5705:15, 5707:16, 5712:25, 5713:5, 5722:4
decks [3] - 5543:15, 5544:15, 5683:17
declaration [1] - 5540:22
declined [1] - 5415:1
declining [2] - 5414:22, 5632:24
decreased [1] - 5557:21
dedicated [1] - 5675:9
deduct [1] - 5406:10
deducted [2] - 5491:12, 5491:13
deduction [2] - 5406:9, 5495:5
deductions [1] - 5585:18
deemed [1] - 5569:1
deep [1] - 5407:21
defend [3] - 5404:5, 5404:10, 5404:22
Defendants [2] - 5378:7, 5378:22
Defendants' [22] - 5379:12, 5379:13, 5379:14, 5379:15, 5379:16, 5379:17, 5379:18, 5517:7, 5677:17, 5681:25, 5682:18, 5687:13, 5688:4, 5688:7, 5705:9, 5705:19, 5705:23, 5712:18, 5712:22, 5715:20, 5716:7, 5716:11
defendants' [1] - 5692:6
defense [3] - 5392:24, 5396:22, 5634:22
Defense [1] - 5661:10
define [6] - 5409:5, 5417:20, 5417:25, 5500:23, 5501:16, 5501:20
defined [4] - 5415:25, 5417:18, 5502:14, 5503:11
definitely [11] - 5426:21, 5436:13, 5436:14, 5438:22, 5449:12, 5465:1, 5490:14, 5534:10, 5609:21, 5622:20, 5630:15
definition [7] -

5417:25, 5499:20, 5500:20, 5501:9, 5501:24, 5542:7, 5548:4

definitions [2] - 5417:19, 5501:3

definitive [1] - 5422:3

degree [18] - 5400:13, 5400:14, 5432:1, 5432:12, 5432:16, 5458:17, 5492:19, 5492:25, 5493:9, 5493:19, 5494:1, 5616:8, 5622:3, 5628:3, 5636:25, 5671:15, 5671:16

Delaware [1] - 5378:22

delay [3] - 5387:12, 5525:16, 5558:12

delete [2] - 5631:15, 5644:20

deleted [1] - 5631:17

deliver [5] - 5420:19, 5533:14, 5534:2, 5534:20, 5536:9

delivered [18] - 5479:24, 5531:17, 5532:11, 5533:4, 5537:8, 5538:2, 5538:16, 5540:25, 5545:11, 5558:7, 5563:10, 5575:25, 5576:1, 5576:5, 5603:20, 5604:10, 5604:19, 5704:13

delivering [5] - 5533:9, 5533:22, 5536:3, 5545:24, 5606:18

delivery [1] - 5479:24

Delores [2] - 5660:16, 5660:18

demonstrate [1] - 5615:11

demonstrative [5] - 5547:13, 5547:21, 5571:11, 5695:16, 5695:20

demonstratives [1] - 5499:23

denied [1] - 5580:20

denying [1] - 5617:2

Department [7] - 5406:16, 5577:20, 5577:23, 5578:5, 5578:10, 5578:16, 5611:5

department [9] - 5431:25, 5432:2,

5469:22, 5472:15, 5526:1, 5595:25, 5632:20, 5660:12, 5704:9

departments [3] - 5472:7, 5472:25, 5702:8

depended [1] - 5502:20

Deposit [1] - 5406:21

deposition [9] - 5465:10, 5465:11, 5528:11, 5528:12, 5544:1, 5589:1, 5643:21, 5644:17, 5666:6

depositions [2] - 5519:2, 5563:20

depressing [1] - 5713:14

depression [1] - 5543:4

depth [1] - 5703:10

DEPUTY [17] - 5380:4, 5397:16, 5397:23, 5398:16, 5464:1, 5559:3, 5559:5, 5559:7, 5634:23, 5635:1, 5635:14, 5635:24, 5671:2, 5686:18, 5686:20, 5686:24, 5719:20

describe [1] - 5699:1

described [2] - 5500:3, 5580:11

describing [1] - 5445:17

description [1] - 5595:8

Description [1] - 5379:11

designed [1] - 5699:2

desk [1] - 5405:7

despite [2] - 5544:14, 5609:4

detail [9] - 5380:25, 5383:8, 5391:7, 5449:20, 5507:6, 5527:16, 5528:4, 5588:4, 5674:14

detailed [1] - 5711:25

details [5] - 5416:22, 5514:15, 5536:16, 5615:1, 5691:16

determination [2] - 5561:20, 5693:20

determine [11] - 5449:5, 5449:25, 5450:24, 5450:25, 5453:8, 5458:4,

5470:2, 5566:5, 5588:20, 5625:23, 5631:6

determined [8] - 5393:13, 5409:9, 5602:17, 5618:15, 5620:2, 5692:18, 5700:12, 5717:25

develop [1] - 5406:24

developed [2] - 5696:13, 5697:1

development [3] - 5637:5, 5637:18, 5673:2

Dew [9] - 5410:17, 5411:5, 5411:21, 5419:20, 5420:6, 5427:1, 5427:2, 5445:16, 5445:18

diabetes [1] - 5707:25

diagnosis [3] - 5417:23, 5418:4, 5418:9

diagnostic [1] - 5489:16

die [1] - 5615:13

differ [2] - 5663:14, 5708:18

difference [35] - 5435:16, 5435:25, 5442:10, 5444:7, 5444:9, 5444:10, 5444:24, 5445:10, 5446:11, 5446:13, 5446:23, 5447:9, 5448:3, 5450:17, 5453:3, 5453:10, 5456:4, 5478:7, 5545:15, 5551:17, 5551:23, 5552:6, 5552:13, 5553:2, 5553:18, 5555:3, 5555:12, 5556:2, 5556:4, 5556:11, 5557:1, 5557:3, 5557:16, 5557:20, 5675:5

differences [4] - 5524:4, 5554:7, 5554:25, 5555:22

different [48] - 5400:11, 5402:14, 5433:16, 5435:18, 5436:4, 5436:15, 5436:16, 5444:18, 5444:23, 5445:7, 5450:8, 5450:11, 5450:13, 5474:14, 5481:1, 5494:25, 5496:15, 5496:21,

5503:12, 5531:19, 5550:19, 5551:12, 5551:14, 5551:20, 5555:8, 5557:7, 5557:12, 5557:13, 5557:15, 5580:25, 5604:23, 5606:1, 5613:13, 5614:13, 5618:3, 5618:4, 5618:19, 5619:8, 5632:13, 5640:3, 5660:19, 5663:10, 5674:20, 5695:22, 5707:14, 5708:8, 5709:14

differently [1] - 5710:8

difficult [3] - 5462:4, 5667:21, 5674:19

difficulty [1] - 5657:13

digesting [1] - 5383:2

dinners [2] - 5452:19, 5615:3

DIRECT [6] - 5379:4, 5379:6, 5379:8, 5398:25, 5636:4, 5671:5

direct [6] - 5394:20, 5525:15, 5525:23, 5526:16, 5539:13, 5713:11

direct-to-consumer [1] - 5394:20

directed [2] - 5394:23, 5558:22

directing [1] - 5391:9

direction [4] - 5455:4, 5515:10, 5535:17, 5558:14

directive [2] - 5681:9, 5700:19

directly [4] - 5619:22, 5657:23, 5657:25, 5681:18

director [2] - 5522:18, 5523:14

disability [4] - 5639:24, 5640:14, 5648:24, 5655:3

disagree [13] - 5510:14, 5510:24, 5520:4, 5520:6, 5520:9, 5523:2, 5523:11, 5533:17, 5534:11, 5537:12, 5551:9, 5554:10, 5554:11

disagreed [1] - 5531:9

disagreement [1] - 5390:11

disagrees [1] -

5475:20

disciplined [1] - 5684:22

disclosed [4] - 5495:6, 5496:17, 5496:19, 5496:22

discount [1] - 5585:12

discounted [1] - 5628:21

discouraging [1] - 5436:2

discovery [6] - 5386:15, 5388:22, 5392:12, 5720:7, 5721:5

discrimination [1] - 5517:24

discuss [2] - 5383:22, 5399:23

discussed [10] - 5468:17, 5537:7, 5564:14, 5566:10, 5607:15, 5628:14, 5633:24, 5639:18, 5666:14, 5685:14

discussing [3] - 5464:12, 5629:17, 5666:16

discussion [2] - 5389:10, 5630:14

discussions [2] - 5536:8, 5666:20

Disease [2] - 5542:14, 5542:16

disease [19] - 5542:20, 5542:23, 5543:3, 5543:5, 5552:16, 5552:19, 5554:18, 5554:20, 5556:3, 5630:25, 5631:9, 5631:14, 5631:18, 5631:20, 5631:24, 5673:4, 5708:14, 5708:19, 5708:25

disease-related [1] - 5631:9

disease-state [3] - 5708:14, 5708:19, 5708:25

dismiss [1] - 5392:18

dispense [1] - 5596:23

dispersion [1] - 5435:11

display [2] - 5517:4, 5593:16

displayed [2] - 5430:3, 5460:16

disproportionate [1] -

5429:11

dispute [8] - 5516:18, 5655:17, 5659:15, 5659:22, 5664:8, 5664:10, 5664:14, 5664:18

disputes [1] - 5391:19

disseminated [1] - 5606:9

distribution [1] - 5466:19

DISTRICT [3] - 5378:1, 5378:1, 5378:12

District [1] - 5380:2

district [8] - 5606:5, 5606:7, 5639:25, 5701:14, 5701:15, 5702:1, 5702:2, 5702:22

district-wide [1] - 5606:5

districts [2] - 5607:4, 5682:7

distrust [1] - 5654:23

divide [7] - 5425:22, 5433:1, 5437:13, 5447:19, 5457:5, 5460:9, 5460:10

divided [6] - 5439:10, 5451:10, 5452:24, 5457:13, 5461:12, 5461:17

dividing [3] - 5431:3, 5432:24, 5451:7

Dividing [1] - 5468:12

doc [1] - 5506:23

dock [1] - 5558:8

doctor [102] - 5400:4, 5416:7, 5416:22, 5417:5, 5418:1, 5423:4, 5423:16, 5430:9, 5442:3, 5444:15, 5448:10, 5451:6, 5451:10, 5451:11, 5454:4, 5454:16, 5455:21, 5456:20, 5456:23, 5456:24, 5457:14, 5458:11, 5466:20, 5466:22, 5467:5, 5467:10, 5467:18, 5467:19, 5468:3, 5468:18, 5476:25, 5499:9, 5499:16, 5500:8, 5500:13, 5500:17, 5501:3, 5507:8, 5510:15, 5510:16, 5510:18, 5511:2, 5513:10, 5522:14, 5532:24,

5535:21, 5541:9, 5541:13, 5542:8, 5545:12, 5546:3, 5546:25, 5550:12, 5561:4, 5565:13, 5566:11, 5567:8, 5567:13, 5569:22, 5569:23, 5570:20, 5571:4, 5571:16, 5571:20, 5572:5, 5572:10, 5572:21, 5573:13, 5580:10, 5595:23, 5597:2, 5597:3, 5597:10, 5597:13, 5597:20, 5598:11, 5602:8, 5602:22, 5603:11, 5608:8, 5609:14, 5613:1, 5614:16, 5614:21, 5615:24, 5615:25, 5620:8, 5620:9, 5620:18, 5620:23, 5621:23, 5630:24, 5631:11, 5633:5, 5633:12, 5711:24, 5716:2

Doctor [4] - 5497:15, 5501:4, 5502:4, 5504:12

doctor's [2] - 5532:23, 5620:19

doctoral [1] - 5402:20

doctorate [3] - 5401:23, 5401:24, 5402:3

doctors [152] - 5409:21, 5410:3, 5410:14, 5411:25, 5416:13, 5416:23, 5416:25, 5422:23, 5424:14, 5425:1, 5425:5, 5425:11, 5425:12, 5426:8, 5427:16, 5428:12, 5428:22, 5429:6, 5429:8, 5429:15, 5429:17, 5433:5, 5433:21, 5438:17, 5439:9, 5441:21, 5442:2, 5443:20, 5444:3, 5445:1, 5445:12, 5446:23, 5447:10, 5449:22, 5452:19, 5454:24, 5455:16, 5455:17, 5455:24, 5456:17, 5459:21, 5460:3, 5460:13, 5460:22, 5461:22, 5462:17, 5462:19, 5466:3,

5466:10, 5467:7, 5467:22, 5468:1, 5476:9, 5476:14, 5476:21, 5503:1, 5503:24, 5504:8, 5504:22, 5506:2, 5507:16, 5508:16, 5513:9, 5533:21, 5534:19, 5534:21, 5534:22, 5538:15, 5545:5, 5547:6, 5550:13, 5551:6, 5551:13, 5552:13, 5552:18, 5552:20, 5553:8, 5554:25, 5555:15, 5555:23, 5556:11, 5557:13, 5557:18, 5564:2, 5567:19, 5569:21, 5570:19, 5571:4, 5572:5, 5573:1, 5591:12, 5595:17, 5596:18, 5597:3, 5597:10, 5597:11, 5598:5, 5598:9, 5598:19, 5598:24, 5599:1, 5599:9, 5599:11, 5599:15, 5599:24, 5600:2, 5600:5, 5600:8, 5600:12, 5600:16, 5600:19, 5601:4, 5601:7, 5601:11, 5601:14, 5601:19, 5603:2, 5607:13, 5608:18, 5609:14, 5609:15, 5612:9, 5612:23, 5613:10, 5613:13, 5614:4, 5614:5, 5614:14, 5616:4, 5621:22, 5623:3, 5624:1, 5624:6, 5624:9, 5627:7, 5630:22, 5631:1, 5631:16, 5631:24, 5631:25, 5632:13, 5632:21, 5642:8, 5642:19, 5657:5, 5707:11, 5711:9, 5711:13, 5711:18, 5718:8

doctors' [3] - 5410:8, 5453:23, 5461:9

document [26] - 5501:1, 5501:7, 5501:9, 5501:15, 5517:16, 5518:11, 5611:21, 5629:3, 5677:5, 5677:10, 5677:11, 5678:14, 5682:2, 5685:5,

5686:9, 5687:16, 5694:16, 5695:15, 5696:5, 5703:11, 5705:11, 5710:16, 5710:20, 5712:7, 5715:22, 5717:20

documentation [3] - 5696:23, 5697:5, 5704:8

documented [4] - 5642:16, 5669:13, 5696:13, 5696:15

documents [24] - 5381:2, 5381:3, 5381:7, 5381:8, 5381:13, 5381:17, 5381:18, 5382:2, 5382:15, 5382:21, 5383:11, 5383:14, 5383:16, 5383:20, 5386:5, 5386:6, 5388:1, 5388:20, 5470:1, 5536:11, 5544:3, 5720:22, 5720:25

Dolisi [7] - 5641:2, 5649:8, 5657:11, 5659:10, 5659:24, 5663:18, 5668:5

dollar [4] - 5473:7, 5474:16, 5474:23, 5480:20

dollars [11] - 5407:18, 5474:1, 5474:2, 5485:17, 5541:17, 5541:19, 5589:11, 5589:18, 5590:15, 5592:12, 5629:1

domain [1] - 5578:8

done [14] - 5390:8, 5454:10, 5471:13, 5507:9, 5553:22, 5567:17, 5569:16, 5582:9, 5593:25, 5642:11, 5691:19, 5706:21, 5722:12

Donna [1] - 5535:1

dosage [3] - 5419:19, 5625:24, 5626:17

dosing [8] - 5415:11, 5419:21, 5420:8, 5481:22, 5481:24, 5488:25, 5490:13, 5608:3

double [2] - 5490:15, 5490:17

doubt [12] - 5389:25, 5426:19, 5430:16, 5430:17, 5430:19, 5433:14, 5438:3,

5439:20, 5456:4, 5471:22, 5478:7, 5670:4

down [23] - 5386:22, 5391:10, 5392:24, 5467:2, 5472:12, 5472:24, 5497:2, 5504:20, 5528:2, 5571:24, 5592:22, 5593:16, 5598:7, 5606:8, 5642:13, 5683:9, 5685:7, 5688:9, 5689:20, 5696:8, 5699:13, 5702:20, 5704:5

downward [1] - 5624:17

Dr [103] - 5413:9, 5413:10, 5413:11, 5413:15, 5413:16, 5413:17, 5413:20, 5418:8, 5462:23, 5463:4, 5464:13, 5464:18, 5465:13, 5468:5, 5468:20, 5469:9, 5475:10, 5475:24, 5508:23, 5509:2, 5509:6, 5509:18, 5509:20, 5510:20, 5510:22, 5510:24, 5511:3, 5511:5, 5511:16, 5511:19, 5513:10, 5522:14, 5522:24, 5523:8, 5523:14, 5523:19, 5524:9, 5524:15, 5527:6, 5527:11, 5527:21, 5528:4, 5529:8, 5529:19, 5529:20, 5530:2, 5530:7, 5530:10, 5530:16, 5530:18, 5531:9, 5531:11, 5541:17, 5550:23, 5554:16, 5556:8, 5556:11, 5564:3, 5564:14, 5564:20, 5564:24, 5565:5, 5565:13, 5566:4, 5566:5, 5566:10, 5566:20, 5570:8, 5570:9, 5570:14, 5570:19, 5570:22, 5571:3, 5573:11, 5573:13, 5574:1, 5574:7, 5575:8, 5575:15, 5576:22, 5591:1, 5595:13, 5596:5, 5596:22, 5614:12, 5614:13, 5615:2,

5619:19, 5620:6,
5620:16, 5621:20,
5623:17, 5623:21,
5623:22, 5623:24,
5623:25, 5631:5,
5687:24, 5689:16,
5689:21, 5716:3
drawer [1] - 5662:18
drew [1] - 5674:15
drink [1] - 5674:21
drug [18] - 5401:12,
5413:21, 5428:12,
5429:18, 5445:2,
5447:16, 5460:24,
5461:13, 5481:7,
5574:23, 5610:3,
5620:9, 5620:20,
5621:22, 5621:23,
5672:11, 5672:19,
5674:2
drugs [18] - 5410:8,
5447:21, 5459:7,
5461:23, 5473:21,
5478:6, 5580:25,
5594:21, 5612:22,
5622:13, 5622:15,
5622:24, 5623:19,
5673:2, 5673:8,
5674:20, 5708:19,
5708:21
dry [1] - 5706:21
due [1] - 5627:1
DULY [3] - 5398:14,
5635:22, 5670:25
duplicated [1] -
5491:11
duplication [5] -
5490:16, 5490:17,
5492:2, 5495:11,
5495:23
during [48] - 5392:4,
5392:17, 5395:11,
5398:6, 5407:11,
5413:25, 5414:5,
5415:16, 5417:8,
5428:12, 5443:18,
5444:1, 5451:16,
5455:18, 5455:22,
5459:2, 5459:22,
5469:11, 5475:4,
5480:5, 5481:2,
5481:15, 5513:14,
5517:11, 5517:18,
5521:13, 5530:4,
5530:12, 5531:4,
5579:16, 5607:14,
5609:20, 5621:1,
5640:16, 5641:23,
5642:3, 5644:16,
5651:21, 5662:18,

5670:2, 5672:14,
5678:7, 5680:13,
5685:9, 5698:3,
5708:7, 5709:20,
5717:1
duty [1] - 5681:16

E

---

ear [1] - 5526:5
early [8] - 5394:6,
5562:24, 5568:16,
5624:19, 5649:15,
5649:16, 5652:5,
5654:14
East [1] - 5378:9
east [2] - 5707:2,
5707:6
eastern [1] - 5606:5
eat [1] - 5446:8
eats [1] - 5446:7
econometric [1] -
5626:25
economical [2] -
5399:18, 5408:16
economically [1] -
5402:5
economics [5] -
5400:15, 5400:17,
5400:20, 5408:3,
5469:9
educate [5] - 5677:2,
5699:4, 5709:7,
5709:10
educated [1] -
5552:21
education [6] -
5492:6, 5492:20,
5493:10, 5493:20,
5494:3, 5636:22
educational [1] -
5697:11
educators [1] -
5441:25
effect [9] - 5445:14,
5469:23, 5478:10,
5479:6, 5479:13,
5517:11, 5610:5,
5610:7, 5610:11
effective [4] - 5475:7,
5475:16, 5602:17,
5714:22
effectively [1] -
5682:11
effectiveness [3] -
5470:12, 5476:8,
5718:16
effects [5] - 5481:7,
5610:2, 5610:16,
5610:17, 5610:18

efficacy [1] - 5678:25
efficient [2] - 5393:23,
5714:22
effort [3] - 5382:14,
5394:19, 5528:4
efforts [9] - 5384:20,
5410:7, 5416:22,
5469:13, 5478:22,
5481:4, 5481:16,
5489:6
eight [7] - 5465:9,
5467:19, 5563:19,
5567:13, 5590:23,
5701:15, 5720:12
either [24] - 5381:21,
5389:23, 5390:7,
5392:17, 5396:4,
5396:18, 5409:7,
5434:11, 5434:16,
5435:7, 5444:16,
5468:7, 5487:1,
5502:12, 5549:15,
5576:15, 5597:8,
5608:7, 5611:15,
5667:17, 5670:2,
5670:23, 5684:11,
5700:8
elaborate [3] -
5430:22, 5511:23,
5533:24
elected [1] - 5489:8
election [1] - 5615:15
eliminate [5] -
5432:11, 5434:20,
5440:11, 5489:2,
5633:7
eliminated [1] -
5452:15
Elizabeth [1] - 5636:1
Ellen [1] - 5564:3
ELMO [9] - 5498:8,
5574:9, 5602:25,
5620:13, 5643:2,
5666:11, 5668:25,
5695:14, 5702:6
email [14] - 5642:16,
5655:20, 5662:16,
5675:20, 5682:4,
5682:10, 5682:21,
5683:9, 5683:10,
5687:19, 5688:9,
5688:21, 5689:17,
5701:14
emailed [1] - 5662:4
emails [4] - 5663:1,
5663:2, 5684:11
emeritus [1] - 5403:4
emotion [1] - 5574:14
emphasize [3] -
5470:25, 5476:16,

5477:17
employed [2] -
5649:14, 5655:19
employee [8] -
5637:18, 5640:7,
5657:24, 5658:10,
5675:14, 5675:15,
5676:5, 5681:15
employees [6] -
5612:3, 5655:9,
5658:2, 5658:6,
5667:8, 5673:16
employment [3] -
5654:14, 5656:19,
5665:8
empty [1] - 5699:14
end [25] - 5384:2,
5386:21, 5389:5,
5389:7, 5392:18,
5393:17, 5399:21,
5496:9, 5544:17,
5560:21, 5561:3,
5561:6, 5562:7,
5573:24, 5595:20,
5624:15, 5630:2,
5649:1, 5649:14,
5661:2, 5679:14,
5719:13, 5721:3,
5721:20, 5721:25
endeavoring [1] -
5694:11
ended [3] - 5412:2,
5681:1, 5703:25
ending [1] - 5675:20
enforcement [1] -
5611:6
enforcing [1] -
5690:12
engage [2] - 5601:25,
5691:12
engaged [1] - 5699:22
engagement [2] -
5408:14, 5589:10
engagements [1] -
5508:17
England [1] - 5710:23
English [5] - 5445:24,
5446:1, 5446:10,
5503:6, 5503:7
Enron [5] - 5407:11,
5407:15, 5407:16,
5407:17, 5407:21
Enron's [1] - 5407:11
ensure [8] - 5679:19,
5689:9, 5690:4,
5691:2, 5691:7,
5691:18, 5692:2,
5702:20
enter [2] - 5558:7,
5559:2

enterprise [1] -
5636:17
enters [5] - 5397:22,
5464:2, 5559:8,
5635:15, 5686:25
entire [12] - 5481:16,
5522:19, 5529:15,
5540:14, 5544:7,
5582:8, 5591:6,
5597:20, 5606:7,
5606:9, 5615:18,
5651:21
entirety [1] - 5691:8
entitled [1] - 5723:5
entry [2] - 5564:3,
5564:13
environment [7] -
5641:4, 5655:5,
5655:8, 5655:12,
5659:5, 5666:21,
5704:16
equal [1] - 5468:13
equipment [1] -
5525:25
errata [4] - 5494:23,
5495:14, 5495:15,
5495:17
especially [3] -
5427:19, 5563:16,
5621:1
ESQUIRE [8] -
5378:14, 5378:15,
5378:15, 5378:16,
5378:16, 5378:19,
5378:20, 5378:20
essentially [4] -
5387:17, 5464:14,
5582:18, 5685:16
established [1] -
5393:7
estimate [12] - 5489:2,
5580:12, 5580:20,
5581:15, 5607:7,
5625:19, 5626:8,
5626:13, 5626:17,
5627:1, 5627:7,
5627:21
estimated [1] - 5589:2
estimates [3] - 5580:8,
5616:8, 5625:22
estimations [1] -
5628:3
et [3] - 5378:3,
5697:14, 5698:11
ethnicity [1] - 5517:21
evacuate [3] -
5525:15, 5525:22,
5558:16
evacuated [2] -
5525:4, 5525:8

evacuation [1] -
5525:19
evaluate [5] - 5591:20,
5592:5, 5592:13,
5702:4, 5702:13
evaluated [3] - 5477:7,
5514:12, 5703:19
evaluates [1] -
5470:19
evaluating [2] -
5692:20, 5702:10
evaluation [3] -
5470:12, 5703:8,
5703:13
Evans [1] - 5542:19
evenly [1] - 5395:20
event [18] - 5416:7,
5416:10, 5416:11,
5423:18, 5434:22,
5443:1, 5446:16,
5500:14, 5500:17,
5542:8, 5542:23,
5549:16, 5575:20,
5576:21, 5598:1,
5602:9, 5685:25,
5690:4
Events [2] - 5542:14,
5542:17
events [19] - 5416:15,
5444:3, 5452:20,
5454:11, 5454:13,
5459:2, 5466:21,
5466:22, 5542:13,
5542:21, 5543:3,
5543:8, 5543:10,
5543:12, 5607:10,
5608:13, 5646:2,
5680:1, 5711:17
eventually [2] -
5402:11, 5514:22
everywhere [2] -
5442:1, 5602:19
evidence [31] -
5379:12, 5379:13,
5379:14, 5379:15,
5379:16, 5379:17,
5379:18, 5470:2,
5517:7, 5518:25,
5519:1, 5528:3,
5531:25, 5532:5,
5540:11, 5583:23,
5584:4, 5584:11,
5585:5, 5585:9,
5592:14, 5628:14,
5638:16, 5644:8,
5677:17, 5682:18,
5688:7, 5705:23,
5710:19, 5712:22,
5716:11
exact [5] - 5427:6,

5587:22, 5599:18,
5614:21, 5620:20
exactly [17] - 5403:3,
5413:2, 5419:17,
5426:17, 5451:5,
5452:10, 5488:10,
5511:17, 5511:20,
5515:12, 5532:15,
5621:9, 5675:19,
5683:7, 5691:20,
5702:13, 5722:10
examination [9] -
5387:9, 5388:3,
5398:7, 5524:21,
5539:14, 5559:15,
5634:2, 5634:6,
5651:11
EXAMINATION [14] -
5379:4, 5379:4,
5379:5, 5379:6,
5379:6, 5379:7,
5379:8, 5398:25,
5497:11, 5594:3,
5636:4, 5653:2,
5668:12, 5671:5
EXAMINATIONS [1] -
5379:2
examine [7] - 5387:9,
5387:23, 5389:23,
5389:24, 5390:6,
5390:7, 5650:24
examined [1] - 5445:4
example [23] -
5431:11, 5431:22,
5509:6, 5533:20,
5544:4, 5555:3,
5565:12, 5565:13,
5566:11, 5566:13,
5571:13, 5575:13,
5577:3, 5581:10,
5591:1, 5604:17,
5614:24, 5615:15,
5616:13, 5617:5,
5690:11, 5705:15,
5715:15
examples [5] -
5431:13, 5560:15,
5567:1, 5567:2,
5624:15
Excel [1] - 5410:24
exception [1] -
5713:25
exceptions [1] -
5699:16
excessively [1] -
5413:2
exchanged [1] -
5684:12
exchanging [1] -
5612:15

excited [1] - 5438:4
exciting [1] - 5559:10
exclude [2] - 5406:8,
5406:13
excluded [3] -
5486:12, 5487:13,
5614:20
excludes [1] - 5490:3
exclusive [1] -
5711:15
excuse [6] - 5453:22,
5462:1, 5482:5,
5504:10, 5603:11,
5712:10
excused [7] - 5388:7,
5633:17, 5670:10,
5719:19, 5719:21,
5719:22, 5719:23
exercise [1] - 5601:25
exercises [2] -
5570:20, 5571:4
exercising [1] -
5579:1
exhibit [4] - 5504:20,
5506:15, 5548:6,
5548:12
Exhibit [36] - 5379:11,
5379:12, 5379:13,
5379:14, 5379:15,
5379:16, 5379:17,
5379:18, 5505:23,
5506:12, 5506:17,
5507:2, 5507:14,
5507:15, 5517:7,
5547:17, 5548:1,
5548:11, 5548:23,
5611:20, 5628:10,
5661:10, 5677:17,
5681:25, 5682:18,
5687:13, 5688:4,
5688:7, 5705:9,
5705:23, 5710:18,
5712:19, 5712:22,
5715:20, 5716:8,
5716:11
exhibits [1] - 5634:5
existence [1] -
5414:14
existing [1] - 5610:18
exists [1] - 5664:13
exit [2] - 5558:7,
5559:2
exits [2] - 5463:19,
5634:24
expanded [1] - 5575:4
expect [2] - 5392:19,
5439:21
expectancy [1] -
5630:7
expected [6] -

5388:10, 5402:20,
5424:23, 5427:16,
5629:13, 5718:18
expended [1] -
5627:16
expense [1] - 5714:20
expenses [3] - 5425:6,
5707:3
expensive [1] -
5595:12
experience [16] -
5492:7, 5492:20,
5493:11, 5493:20,
5494:3, 5613:14,
5664:1, 5685:23,
5686:4, 5692:14,
5693:2, 5697:13,
5697:18, 5707:10,
5718:8, 5718:24
experienced [4] -
5412:19, 5413:4,
5486:23, 5487:3
expert [33] - 5394:23,
5395:7, 5408:16,
5462:21, 5465:14,
5467:18, 5469:8,
5475:20, 5475:22,
5478:8, 5494:22,
5512:21, 5552:16,
5554:1, 5570:4,
5570:6, 5570:23,
5578:4, 5579:9,
5579:11, 5595:1,
5602:17, 5611:4,
5622:6, 5622:8,
5623:8, 5630:24,
5631:12, 5631:13,
5631:18, 5631:21,
5632:6, 5633:8
expert's [2] - 5464:13,
5555:18
experts [10] - 5395:1,
5469:12, 5475:15,
5475:21, 5477:5,
5552:16, 5556:3,
5630:25, 5691:20,
5691:22
explain [20] - 5412:2,
5420:14, 5425:10,
5434:24, 5437:3,
5440:14, 5440:22,
5445:22, 5447:7,
5447:12, 5460:12,
5508:12, 5546:16,
5546:21, 5603:1,
5603:9, 5648:22,
5649:8, 5652:9,
5690:17
explained [1] - 5620:6
explains [1] - 5382:19

exploring [1] -
5641:16
exposure [2] -
5470:21, 5470:23
extended [1] -
5525:16
extending [1] -
5517:23
extent [4] - 5428:17,
5619:10, 5650:2,
5703:24
extra [1] - 5558:12
extraordinarily [3] -
5574:7, 5574:11,
5574:16
extremely [1] -
5602:18
eyes [4] - 5380:24,
5382:21, 5383:11,
5720:20

F

facing [1] - 5680:16
fact [28] - 5395:3,
5435:21, 5497:20,
5507:25, 5509:11,
5512:5, 5512:9,
5515:1, 5518:21,
5519:8, 5533:13,
5543:14, 5544:14,
5547:6, 5549:24,
5551:2, 5554:1,
5555:14, 5555:22,
5557:2, 5557:17,
5568:22, 5579:7,
5580:9, 5595:3,
5595:15, 5656:7,
5662:15
factor [3] - 5445:9,
5582:22, 5584:20
factors [9] - 5444:17,
5445:5, 5445:13,
5550:19, 5551:12,
5551:16, 5551:18,
5697:9
facts [1] - 5583:23
faculty [2] - 5401:25,
5699:16
fail [1] - 5674:25
failures [1] - 5487:4
fair [70] - 5382:18,
5385:4, 5391:14,
5391:15, 5394:12,
5396:11, 5416:16,
5422:13, 5436:9,
5463:6, 5483:16,
5484:19, 5488:15,
5488:23, 5501:13,
5530:16, 5530:18,

5531:10, 5543:11, 5555:24, 5555:25, 5585:17, 5593:24, 5598:2, 5598:3, 5601:18, 5613:5, 5630:4, 5639:11, 5639:12, 5639:14, 5654:16, 5655:2, 5656:9, 5657:15, 5658:7, 5658:18, 5660:21, 5661:7, 5662:24, 5663:12, 5663:13, 5665:1, 5665:4, 5665:5, 5675:4, 5678:24, 5680:24, 5690:11, 5692:11, 5692:18, 5693:11, 5696:24, 5697:2, 5698:14, 5702:14, 5702:21, 5703:18, 5703:21, 5706:13, 5709:15, 5711:4, 5711:22, 5712:1, 5714:3, 5714:4, 5717:12, 5717:22, 5717:24

fairly [3] - 5389:20, 5676:20, 5718:20

fall [5] - 5435:1, 5612:9, 5638:3, 5638:8, 5643:12

fallacy [1] - 5431:23

False [7] - 5412:12, 5578:6, 5578:9, 5612:1, 5612:6, 5612:16, 5665:23

false [2] - 5578:1, 5611:14

familiar [9] - 5504:21, 5506:14, 5563:6, 5586:22, 5660:5, 5707:21, 5708:15, 5709:3, 5716:3

familiarity [1] - 5478:5

familiarize [1] - 5705:5

fantastic [1] - 5624:21

far [12] - 5440:23, 5453:12, 5488:21, 5512:13, 5513:1, 5544:24, 5546:18, 5557:7, 5560:9, 5691:15, 5691:16, 5708:1

fast [1] - 5432:9

faster [2] - 5414:25, 5721:16

fat [1] - 5674:21

fault [2] - 5651:8, 5655:24

FDA [7] - 5386:3, 5540:6, 5679:10, 5680:3, 5680:8, 5680:10, 5718:19

FDA-approved [2] - 5679:10, 5718:19

FDA/DDMAC [1] - 5707:15

FDIC [7] - 5406:19, 5406:20, 5406:23, 5406:24, 5406:25, 5408:10

Fe [1] - 5693:19

featured [1] - 5405:3

Federal [1] - 5406:20

FEDERAL [1] - 5723:1

federal [8] - 5411:7, 5412:5, 5482:20, 5518:12, 5558:20, 5558:25, 5611:7, 5611:13

fee [1] - 5710:3

feedback [2] - 5525:15, 5680:20

fees [2] - 5425:5, 5425:6

felt [10] - 5385:16, 5639:7, 5640:20, 5640:22, 5641:6, 5647:25, 5667:19, 5667:21, 5668:20, 5675:6

Fernandez [1] - 5640:14

few [31] - 5386:19, 5390:9, 5399:8, 5403:24, 5406:12, 5418:1, 5420:3, 5420:25, 5446:3, 5446:12, 5448:9, 5448:21, 5452:11, 5455:25, 5471:17, 5489:24, 5505:11, 5559:24, 5592:23, 5593:6, 5601:22, 5605:25, 5614:1, 5614:2, 5623:7, 5623:10, 5671:8, 5706:4, 5708:8, 5716:18, 5719:12

fewer [2] - 5456:13, 5468:1

Field [1] - 5700:8

field [11] - 5445:23, 5517:1, 5557:19, 5622:17, 5627:17, 5636:15, 5637:7, 5637:16, 5648:7, 5648:14

Field-based [1] -

5700:8

fielding [1] - 5637:18

fields [2] - 5627:8, 5627:9

Fights [1] - 5404:20

figure [7] - 5383:23, 5558:10, 5603:10, 5603:11, 5614:18, 5649:25, 5650:17

figuring [1] - 5582:3

file [7] - 5385:1, 5394:11, 5395:14, 5396:4, 5659:1, 5659:5, 5665:23

filed [2] - 5383:2, 5395:6

files [2] - 5662:15, 5662:19

filing [3] - 5389:7, 5662:17, 5662:21

final [9] - 5384:9, 5384:14, 5386:17, 5386:21, 5492:3, 5494:23, 5495:6, 5686:12, 5700:11

finally [5] - 5411:23, 5481:22, 5493:22, 5588:2, 5630:20

finance [6] - 5402:6, 5402:7, 5405:15, 5407:21, 5472:7, 5472:15

Finance [1] - 5405:14

finances [1] - 5400:9

financial [4] - 5400:10, 5401:19, 5402:9, 5690:25

financing [2] - 5407:19, 5472:24

fine [22] - 5387:21, 5388:6, 5390:16, 5391:6, 5392:2, 5421:21, 5483:13, 5492:15, 5506:13, 5506:25, 5507:19, 5509:18, 5510:24, 5512:1, 5523:3, 5531:14, 5532:8, 5536:1, 5567:23, 5568:4, 5668:1, 5720:16

Fine [1] - 5631:15

finish [1] - 5721:18

finishing [1] - 5628:8

firm [12] - 5410:20, 5470:6, 5589:9, 5589:13, 5589:14, 5589:18, 5592:11, 5592:23, 5593:4, 5594:9, 5594:15

first [63] - 5387:1, 5392:4, 5393:11, 5401:9, 5404:21, 5408:19, 5409:21, 5410:2, 5416:6, 5419:5, 5419:8, 5420:16, 5420:18, 5422:25, 5423:3, 5423:9, 5424:4, 5424:5, 5424:13, 5434:7, 5455:10, 5461:17, 5472:19, 5474:22, 5478:15, 5479:14, 5479:23, 5520:22, 5529:1, 5535:2, 5535:12, 5535:22, 5550:1, 5569:4, 5569:9, 5570:5, 5573:13, 5573:23, 5597:22, 5597:25, 5620:11, 5620:19, 5636:14, 5637:6, 5638:14, 5643:13, 5648:25, 5650:9, 5650:12, 5651:21, 5656:23, 5671:16, 5672:4, 5672:22, 5678:3, 5678:18, 5680:6, 5688:9, 5699:13, 5701:3, 5703:7

Fisher [1] - 5378:8

fits [2] - 5501:3, 5551:3

five [20] - 5453:5, 5455:8, 5456:2, 5460:4, 5528:13, 5548:13, 5548:20, 5564:8, 5567:24, 5587:18, 5589:25, 5590:18, 5591:17, 5594:9, 5600:2, 5602:12, 5625:25, 5707:2, 5721:24, 5722:3

five-plus [1] - 5600:2

five-to-ten-minute [1] - 5722:3

fix [2] - 5621:16, 5647:1

fixing [1] - 5666:10

flat [1] - 5632:24

flesh [1] - 5700:22

flip [3] - 5706:3, 5712:24, 5712:25

FLOM [1] - 5378:19

flow [2] - 5513:23, 5613:13

flying [2] - 5707:3, 5707:4

focus [11] - 5412:24, 5423:23, 5552:4, 5603:7, 5612:25, 5613:14, 5613:22, 5615:11, 5651:10, 5697:12, 5710:7

focused [7] - 5394:19, 5479:2, 5603:7, 5614:3, 5710:12, 5713:17, 5714:14

folks [31] - 5380:5, 5380:16, 5386:22, 5396:24, 5397:24, 5421:15, 5450:21, 5463:16, 5521:20, 5526:9, 5549:20, 5549:24, 5558:3, 5559:9, 5583:24, 5590:4, 5619:7, 5634:20, 5635:16, 5640:9, 5675:8, 5684:8, 5686:16, 5687:1, 5687:19, 5688:24, 5689:14, 5701:21, 5719:13, 5719:25, 5722:11

follow [5] - 5483:15, 5662:25, 5663:2, 5664:6, 5717:13

follow-up [3] - 5662:25, 5663:2, 5664:6

followed [1] - 5569:1

following [5] - 5495:25, 5502:5, 5610:15, 5611:25, 5612:14

FOLLOWS [3] - 5398:15, 5635:23, 5671:1

follows [1] - 5517:18

food [2] - 5674:21

footnote [1] - 5462:5

footnotes [1] - 5440:23

FOR [1] - 5378:1

forbidden [2] - 5698:19, 5710:14

force [11] - 5410:7, 5444:4, 5446:18, 5453:22, 5454:21, 5455:17, 5476:9, 5477:6, 5602:13, 5602:16, 5637:16

forecasts [1] - 5609:5

foregoing [1] - 5723:4

forget [3] - 5439:7, 5477:19, 5487:25

forgetting [1] - 5646:25

forgot [2] - 5435:7,
5715:2
former [1] - 5610:12
forms [1] - 5417:15
forth [4] - 5382:5,
5382:15, 5393:15,
5585:8
fortunately [1] -
5630:6
forward [2] - 5479:24,
5585:5
forwarded [1] -
5619:24
Foundation [1] -
5523:14
four [21] - 5468:13,
5471:17, 5481:1,
5503:2, 5503:11,
5504:1, 5504:23,
5505:4, 5506:1,
5530:16, 5530:21,
5530:24, 5531:3,
5531:4, 5531:11,
5535:5, 5538:8,
5589:5, 5637:1,
5707:1
fourth [4] - 5457:21,
5457:23, 5685:7
Fox [1] - 5405:5
frame [5] - 5455:15,
5484:5, 5492:4,
5492:14, 5638:8
frames [1] - 5417:17
framework [2] -
5417:14, 5420:22
framing [1] - 5416:6
Frank [2] - 5609:7,
5660:2
frank [2] - 5387:12,
5394:17
frankly [3] - 5410:20,
5629:19, 5721:16
fraud [1] - 5407:23
free [1] - 5517:24
freelancer [1] -
5675:25
French [1] - 5671:15
frequently [3] -
5570:24, 5605:21,
5608:18
Friday [2] - 5675:15,
5714:19
friendly [4] - 5536:4,
5536:12, 5537:2,
5608:18
friends [1] - 5594:8
front [9] - 5388:23,
5392:8, 5504:15,
5506:6, 5506:22,
5558:11, 5607:18,

5607:21, 5687:17
full [7] - 5401:5,
5401:6, 5401:25,
5402:12, 5402:13,
5402:24, 5654:7
full-time [5] - 5401:5,
5401:6, 5401:25,
5402:24, 5654:7
function [1] - 5561:24
functions [1] -
5636:17
funding [2] - 5581:17,
5581:21
furnish [1] - 5683:17
future [3] - 5573:2,
5573:3, 5689:19
Fuzeon [1] - 5672:19

G

Gail [1] - 5673:10
games [1] - 5621:3
gap [1] - 5568:22
Gates [1] - 5431:15
gathered [1] - 5704:14
gathering [2] - 5386:4,
5386:6
Geez [1] - 5633:19
geez [1] - 5673:17
gender [2] - 5517:21,
5517:22
general [8] - 5543:5,
5606:21, 5608:22,
5608:23, 5621:3,
5640:15, 5706:9,
5714:19
generalist [1] - 5672:5
generally [8] -
5464:21, 5515:16,
5555:4, 5599:10,
5599:16, 5599:19,
5631:2, 5684:11
generated [3] -
5425:25, 5477:1,
5718:2
generating [1] -
5714:21
geniuses [1] -
5441:13
gentleman [1] -
5448:14
Geoff [1] - 5380:19
GEOFFREY [1] -
5378:20
geographic [1] -
5694:24
geography [9] -
5432:1, 5432:8,
5432:10, 5432:12,
5432:16, 5701:18,

5701:23, 5702:23
German [1] - 5441:1
given [32] - 5392:14,
5409:9, 5413:1,
5413:3, 5416:24,
5418:25, 5421:24,
5422:5, 5444:9,
5445:11, 5492:6,
5492:19, 5493:10,
5493:19, 5494:2,
5494:23, 5513:7,
5529:14, 5530:3,
5530:6, 5530:12,
5530:17, 5531:5,
5531:6, 5535:20,
5543:10, 5543:15,
5543:18, 5626:16,
5627:25, 5629:16,
5691:15
glad [1] - 5448:13
glare [1] - 5620:17
Glatt [31] - 5413:9,
5413:10, 5413:11,
5413:15, 5413:17,
5413:20, 5418:8,
5509:2, 5509:6,
5509:18, 5509:20,
5510:20, 5510:22,
5510:24, 5511:3,
5511:5, 5511:16,
5511:19, 5513:10,
5550:23, 5570:8,
5570:9, 5570:14,
5570:19, 5570:22,
5571:3, 5619:19,
5620:6, 5620:16,
5621:10, 5621:20
Glatt's [2] - 5413:16,
5508:23
Glenn [1] - 5610:22
Goldman [1] -
5407:20
govern [2] - 5700:6,
5706:18
governance [1] -
5707:17
governed [4] - 5678:2,
5678:9, 5704:21,
5707:14
government [90] -
5411:7, 5411:8,
5411:21, 5412:2,
5412:6, 5414:2,
5414:4, 5415:16,
5419:22, 5424:7,
5425:14, 5426:10,
5426:15, 5427:17,
5429:21, 5443:19,
5444:1, 5445:3,
5460:2, 5478:20,

5479:8, 5479:22,
5480:13, 5480:21,
5482:11, 5482:20,
5483:2, 5483:19,
5483:20, 5484:2,
5484:6, 5484:8,
5485:4, 5485:16,
5486:3, 5491:9,
5492:8, 5493:23,
5498:11, 5500:21,
5500:23, 5501:6,
5501:20, 5513:21,
5514:3, 5514:19,
5514:23, 5515:3,
5515:8, 5515:18,
5515:20, 5515:24,
5516:3, 5516:5,
5517:16, 5518:2,
5518:5, 5518:12,
5518:13, 5544:18,
5545:8, 5560:23,
5561:15, 5561:20,
5566:1, 5566:23,
5576:24, 5577:10,
5579:17, 5583:21,
5585:13, 5585:16,
5586:20, 5603:12,
5611:7, 5611:13,
5611:15, 5611:24,
5612:4, 5612:13,
5613:12, 5613:15,
5613:23, 5619:16,
5621:8, 5622:2,
5624:18, 5637:1,
5665:23
Government [3] -
5399:19, 5409:15
**government-
reimbursed** [1] -
5483:20
governs [1] - 5677:22
grab [2] - 5593:13,
5635:13
grad [3] - 5652:3,
5652:6, 5654:8
grade [4] - 5441:14,
5441:18, 5616:11,
5630:24
grades [4] - 5441:9,
5441:11, 5458:8,
5616:10
graduated [1] -
5640:23
graduates [1] - 5432:3
graduating [1] -
5431:24
Graham [2] - 5535:1,
5535:13
graph [2] - 5432:18,
5575:23

graphically [2] -
5430:4, 5460:16
gratuities [1] - 5691:1
greater [2] - 5442:13,
5455:8
green [1] - 5439:12
grew [3] - 5414:23,
5671:10, 5671:12
grid [1] - 5661:2
grooms [3] - 5607:1,
5608:7, 5608:11
Grooms [1] - 5537:24
grooms's [1] -
5607:23
ground [1] - 5665:13
grounds [2] - 5391:13,
5391:25
Group [1] - 5403:19
group [12] - 5429:22,
5437:18, 5443:17,
5443:24, 5444:11,
5557:18, 5624:8,
5679:13, 5687:20,
5693:24, 5695:2,
5695:7
groups [24] - 5437:14,
5439:10, 5443:16,
5444:8, 5444:13,
5445:12, 5445:13,
5453:10, 5453:11,
5455:8, 5468:13,
5551:18, 5551:20,
5552:13, 5554:25,
5555:4, 5555:9,
5555:23, 5557:4,
5557:13, 5557:16,
5557:20, 5702:8,
5709:9
guess [4] - 5395:3,
5495:21, 5561:19,
5680:24
guidance [4] -
5421:25, 5422:6,
5422:11, 5683:12
Guide [2] - 5405:10,
5405:18
Guidelines [1] -
5706:8
guidelines [1] -
5706:10
guy [6] - 5418:22,
5426:25, 5448:6,
5448:15, 5451:13,
5625:8
guys [10] - 5383:6,
5384:8, 5391:16,
5395:13, 5448:17,
5497:1, 5558:11,
5629:20, 5720:1,
5721:12

H

habits [4] - 5458:22, 5461:9, 5468:23, 5632:19
half [12] - 5400:7, 5423:11, 5451:18, 5451:19, 5452:6, 5478:15, 5512:22, 5590:15, 5592:11, 5637:2
halfway [1] - 5696:8
hand [26] - 5426:2, 5426:6, 5430:20, 5430:25, 5431:6, 5438:10, 5439:12, 5439:15, 5441:23, 5441:24, 5443:24, 5444:20, 5444:22, 5447:23, 5448:2, 5448:8, 5455:5, 5456:11, 5461:10, 5465:24, 5482:4, 5482:5, 5482:24, 5507:1, 5548:14
handful [1] - 5519:2
handle [2] - 5410:21, 5411:3
happy [3] - 5506:17, 5545:8, 5636:7
hard [4] - 5548:2, 5607:16, 5622:4, 5675:8
Harvard [4] - 5400:2, 5401:21, 5402:1, 5402:3
haunt [1] - 5625:20
HAVING [3] - 5398:14, 5635:22, 5670:25
Hawaii [4] - 5594:5, 5595:1, 5595:3, 5595:12
HC [1] - 5684:18
HCC [3] - 5642:15, 5683:12, 5706:17
head [3] - 5429:3, 5625:4, 5636:17
health [24] - 5476:25, 5478:1, 5581:2, 5594:22, 5637:3, 5672:4, 5674:5, 5677:2, 5679:16, 5681:20, 5684:18, 5684:19, 5685:10, 5692:23, 5693:25, 5694:17, 5695:4, 5695:7, 5695:9, 5698:10, 5699:4, 5704:19
Health [1] - 5689:6

hear [14] - 5394:16, 5395:8, 5399:10, 5462:22, 5463:5, 5605:16, 5607:14, 5609:22, 5634:21, 5661:18, 5661:20, 5662:2, 5722:2
heard [41] - 5481:2, 5503:16, 5521:13, 5522:11, 5522:20, 5522:24, 5524:3, 5524:8, 5524:16, 5525:13, 5529:8, 5529:13, 5531:21, 5534:16, 5535:1, 5535:7, 5535:16, 5540:4, 5563:3, 5573:12, 5605:5, 5605:25, 5609:15, 5609:23, 5637:21, 5640:13, 5641:5, 5642:25, 5643:1, 5647:11, 5647:20, 5653:18, 5653:21, 5653:22, 5656:3, 5661:13, 5672:14, 5676:16, 5680:9, 5708:7, 5709:20
hearing [3] - 5416:23, 5525:11, 5673:1
heavy [1] - 5407:21
held [2] - 5380:1, 5542:14
hell [4] - 5667:18, 5667:22, 5668:2, 5668:5
hello [1] - 5594:4
help [6] - 5470:20, 5577:10, 5641:2, 5641:12, 5661:25, 5667:9
helped [1] - 5689:8
helpful [2] - 5671:15, 5722:1
helping [2] - 5594:10, 5637:19
helps [2] - 5437:8, 5577:4
herself [1] - 5644:6
hi [1] - 5688:14
high [9] - 5431:17, 5435:19, 5448:20, 5512:16, 5517:23, 5623:20, 5674:20, 5674:21, 5695:22
high-quality [1] - 5517:23
higher [9] - 5427:18, 5427:19, 5433:13, 5440:5, 5554:19,

5555:15, 5592:22, 5630:24, 5693:16
highest [1] - 5431:24
highlighted [1] - 5554:7
highly [3] - 5389:25, 5617:10, 5627:24
hijacked [2] - 5566:14, 5592:18
hijacks [1] - 5579:8
himself [6] - 5509:3, 5509:11, 5512:21, 5596:7, 5619:19, 5623:18
hire [1] - 5469:12
hired [6] - 5462:23, 5469:10, 5470:11, 5519:9, 5587:12, 5592:17
history [1] - 5490:1
hit [1] - 5719:8
HIV [46] - 5418:25, 5429:7, 5443:17, 5443:25, 5447:16, 5461:13, 5509:11, 5512:15, 5512:18, 5512:22, 5516:11, 5516:12, 5516:16, 5516:19, 5516:20, 5517:10, 5517:17, 5517:20, 5527:13, 5543:4, 5551:2, 5570:19, 5571:3, 5574:18, 5621:1, 5622:13, 5630:6, 5671:19, 5672:11, 5672:21, 5672:22, 5673:5, 5674:5, 5674:6, 5674:15, 5674:17, 5676:20, 5676:22, 5693:18, 5699:7, 5707:24, 5708:23, 5709:10
HIV/AIDS [1] - 5622:12
hold [3] - 5457:14, 5650:3, 5672:1
holds [1] - 5632:14
Holshoe [4] - 5536:2, 5536:16, 5536:17, 5537:9
Holshoe's [1] - 5536:8
home [1] - 5672:25
honest [2] - 5639:7, 5654:20
honestly [1] - 5473:3
Honor [102] - 5380:9, 5380:17, 5380:19, 5382:4, 5382:24, 5383:13, 5384:12, 5384:19, 5385:25,

5386:10, 5387:2, 5387:11, 5388:4, 5389:1, 5390:12, 5390:19, 5391:12, 5391:23, 5393:2, 5394:10, 5394:17, 5394:19, 5396:1, 5396:13, 5396:23, 5397:1, 5397:4, 5397:12, 5397:13, 5397:14, 5397:19, 5398:10, 5398:12, 5398:24, 5421:1, 5421:5, 5421:8, 5421:14, 5421:19, 5422:8, 5463:15, 5463:23, 5464:10, 5494:9, 5494:10, 5494:14, 5494:21, 5496:16, 5497:5, 5497:8, 5499:22, 5507:1, 5517:3, 5527:3, 5537:22, 5557:24, 5583:22, 5585:10, 5585:25, 5586:13, 5586:16, 5593:12, 5593:18, 5593:20, 5594:1, 5613:3, 5616:18, 5616:21, 5617:10, 5618:11, 5629:2, 5633:23, 5634:4, 5634:7, 5635:3, 5635:18, 5636:3, 5638:16, 5649:19, 5650:9, 5651:15, 5653:1, 5668:7, 5668:10, 5670:14, 5670:18, 5677:14, 5682:15, 5686:14, 5687:5, 5688:3, 5705:19, 5712:18, 5716:7, 5719:3, 5720:4, 5720:5, 5720:14, 5721:16, 5722:10, 5722:13, 5722:16
Honor's [1] - 5496:4
HONORABLE [1] - 5378:11
Honorable [1] - 5380:1
honoraria [6] - 5424:18, 5424:21, 5424:22, 5691:5, 5693:9, 5693:17
hope [3] - 5395:5, 5397:25, 5595:22
hoped [1] - 5675:4
hopefully [2] - 5384:2,

5557:23
horrible [1] - 5674:18
Hoskinson [4] - 5565:13, 5566:5, 5623:21, 5623:24
hostile [6] - 5404:23, 5655:4, 5655:7, 5655:12, 5659:5, 5666:21
hot [1] - 5608:3
hotel [3] - 5594:12, 5690:23, 5704:15
hour [7] - 5587:12, 5588:18, 5595:4, 5661:23, 5665:2, 5686:12, 5706:19
hour-long [1] - 5661:23
hourly [2] - 5587:21, 5588:23
hours [23] - 5441:5, 5441:10, 5441:18, 5458:8, 5526:3, 5588:23, 5588:24, 5589:2, 5589:6, 5589:23, 5590:9, 5590:10, 5590:12, 5616:10, 5656:7, 5658:15, 5661:22, 5662:3, 5662:5, 5662:6, 5664:24, 5665:3, 5679:14
House [1] - 5406:1
housekeeping [4] - 5384:4, 5386:25, 5389:4, 5392:17
houses [1] - 5594:25
HR [24] - 5636:12, 5636:16, 5637:3, 5637:5, 5637:9, 5637:16, 5637:17, 5639:9, 5642:17, 5643:12, 5643:16, 5643:22, 5643:23, 5645:22, 5648:14, 5658:10, 5659:20, 5660:9, 5660:12, 5660:20, 5660:22, 5662:17, 5662:21, 5669:12
Hsu [20] - 5468:5, 5522:14, 5522:24, 5523:8, 5523:14, 5523:19, 5541:17, 5573:11, 5573:13, 5573:18, 5574:1, 5574:7, 5575:8, 5591:1, 5595:13, 5595:24, 5596:5, 5596:22, 5623:17,

5716:3
Hsu's [1] - 5575:10
human [4] - 5644:18,
5645:8, 5657:21,
5708:24
hundred [6] - 5434:14,
5539:25, 5590:10,
5609:13, 5609:15,
5666:13
hundreds [3] -
5410:22, 5658:3,
5708:2
hypoglycemia [3] -
5489:17, 5489:23,
5490:4
hypoglycemic [1] -
5489:15

I

i' [1] - 5405:3
Ian [13] - 5410:17,
5411:5, 5411:21,
5418:22, 5419:20,
5426:25, 5427:1,
5427:2, 5445:16,
5445:18, 5455:10,
5514:5, 5627:3
ID [2] - 5571:25,
5614:16
idea [18] - 5405:8,
5406:8, 5407:17,
5435:6, 5441:2,
5451:9, 5504:15,
5537:1, 5548:6,
5560:20, 5562:6,
5574:2, 5574:17,
5581:18, 5581:23,
5586:19, 5622:19,
5721:12
identical [4] -
5439:16, 5442:12,
5632:13
identically [1] -
5415:12
identification [1] -
5615:6
identified [17] -
5382:10, 5482:10,
5504:24, 5514:1,
5515:9, 5515:24,
5516:11, 5516:15,
5518:5, 5519:2,
5544:8, 5544:11,
5549:11, 5550:8,
5551:11, 5575:15,
5689:23
identify [6] - 5419:19,
5419:20, 5424:13,
5573:11, 5573:12,

5573:13
identifying [1] -
5513:5
identity [2] - 5517:22,
5581:5
ignore [1] - 5584:3
ignored [3] - 5647:14,
5648:12, 5659:18
illegal [1] - 5514:24
illustrate [1] - 5714:13
imagine [2] - 5530:19,
5667:20
imagined [1] -
5721:16
impact [10] - 5463:10,
5465:15, 5469:13,
5471:7, 5475:8,
5475:17, 5477:15,
5477:25, 5512:18,
5604:4
impacted [1] -
5526:14
implement [1] -
5691:22
implementation [1] -
5691:13
implemented [2] -
5692:15, 5700:19
implementing [2] -
5681:9, 5698:21
implies [1] - 5430:6
importance [1] -
5442:12
important [9] -
5408:18, 5416:20,
5437:19, 5445:5,
5488:18, 5569:10,
5592:3, 5623:14,
5705:3
impose [1] - 5391:7
impossibility [1] -
5669:15
impossible [1] -
5669:18
impressed [2] -
5477:9, 5602:19
impression [4] -
5569:5, 5608:22,
5608:23, 5641:8
in-depth [1] - 5703:10
in-person [1] -
5661:22
Inc [1] - 5689:3
incidents [1] - 5684:8
inclination [1] -
5391:1
include [6] - 5489:8,
5497:25, 5498:6,
5498:18, 5612:7,
5697:10

included [17] - 5385:9,
5385:11, 5385:12,
5487:12, 5498:13,
5499:8, 5499:10,
5499:15, 5502:7,
5502:15, 5502:17,
5534:9, 5576:7,
5614:17, 5614:22,
5619:16, 5622:1
includes [2] - 5575:4,
5581:23
including [12] -
5402:9, 5404:4,
5470:15, 5470:16,
5521:13, 5534:7,
5592:23, 5636:16,
5698:9, 5699:4,
5716:20, 5718:15
inclusive [1] - 5691:1
income [3] - 5431:16,
5431:18, 5431:24
inconsistent [3] -
5523:8, 5528:8,
5528:10
incorporated [1] -
5681:2
incorrect [2] -
5463:10, 5556:16
incorrectly [1] -
5541:19
increase [5] - 5471:4,
5476:2, 5476:3,
5698:23, 5714:5
increasing [1] -
5636:12
incremental [3] -
5472:1, 5473:17,
5477:1
independent [3] -
5578:25, 5592:13,
5592:19
indicate [2] - 5442:24,
5476:1
indicated [4] - 5413:1,
5414:7, 5416:8,
5480:23
indicates [4] -
5449:10, 5449:13,
5450:11, 5683:12
indication [4] -
5388:19, 5390:2,
5413:12, 5575:5
indirectly [1] -
5407:23
individual [8] -
5514:11, 5551:6,
5551:7, 5573:19,
5582:4, 5624:12,
5696:15, 5712:14
individualized [1] -

5551:12
individually [3] -
5597:17, 5615:24,
5616:4
inducements [1] -
5479:1
industries [2] -
5470:8, 5637:3
industry [5] - 5602:20,
5617:2, 5618:7,
5691:15
inexpensive [1] -
5714:23
infections [1] -
5517:20
infectious [12] -
5552:16, 5552:19,
5554:18, 5554:20,
5556:3, 5630:24,
5631:8, 5631:14,
5631:18, 5631:20,
5631:24, 5673:3
inference [1] - 5720:8
inflammatory [2] -
5617:3, 5617:11
influence [19] -
5416:23, 5417:15,
5423:4, 5423:12,
5423:13, 5444:20,
5452:25, 5457:18,
5483:9, 5500:23,
5505:8, 5522:17,
5597:21, 5614:9,
5615:22, 5615:23,
5616:3, 5631:13,
5710:7
Influenced [1] -
5461:2
influenced [129] -
5409:5, 5416:1,
5416:5, 5416:9,
5417:18, 5422:24,
5423:10, 5443:19,
5443:22, 5444:2,
5444:25, 5445:1,
5445:2, 5445:7,
5445:8, 5446:15,
5447:3, 5447:4,
5447:22, 5447:24,
5447:25, 5448:2,
5448:8, 5448:19,
5448:23, 5449:15,
5449:22, 5449:23,
5450:8, 5451:2,
5451:11, 5461:11,
5461:15, 5461:22,
5462:9, 5462:12,
5465:22, 5465:23,
5466:5, 5466:15,
5466:23, 5468:12,

5469:5, 5469:6,
5479:14, 5482:15,
5482:23, 5482:25,
5483:3, 5484:24,
5485:9, 5485:18,
5485:23, 5499:16,
5499:20, 5499:21,
5500:3, 5500:20,
5501:3, 5501:17,
5501:20, 5501:24,
5502:6, 5502:10,
5502:15, 5503:5,
5504:4, 5505:5,
5505:6, 5505:10,
5505:18, 5507:21,
5508:20, 5542:7,
5542:9, 5545:12,
5545:15, 5547:1,
5548:3, 5549:11,
5550:1, 5550:7,
5550:12, 5551:24,
5551:25, 5552:7,
5553:3, 5553:4,
5553:18, 5553:19,
5553:23, 5554:2,
5554:8, 5554:18,
5554:19, 5564:14,
5564:24, 5568:13,
5569:18, 5569:22,
5571:16, 5572:6,
5572:17, 5574:3,
5577:12, 5579:22,
5579:23, 5580:16,
5595:21, 5596:7,
5598:15, 5600:23,
5601:1, 5613:2,
5619:14, 5620:8,
5630:23, 5631:20,
5631:24, 5631:25
influencing [2] -
5416:10, 5568:18
info [2] - 5526:16,
5526:23
Information [1] -
5678:23
information [43] -
5407:14, 5411:5,
5411:14, 5411:15,
5418:3, 5418:7,
5420:6, 5424:3,
5430:23, 5454:19,
5505:13, 5507:14,
5525:9, 5525:21,
5525:22, 5525:24,
5549:10, 5564:6,
5568:24, 5568:25,
5579:21, 5580:5,
5607:6, 5607:8,
5608:9, 5625:18,
5625:19, 5626:19,
5626:22, 5628:24,

5666:17, 5679:6,
5679:11, 5679:20,
5684:12, 5685:13,
5698:18, 5702:16,
5702:24, 5703:1,
5711:5, 5713:17,
5714:18
informed [1] - 5511:2
informing [1] -
5510:19
infraction [2] -
5681:17, 5684:24
infrequently [1] -
5510:22
inhibitor [1] - 5672:6
initial [3] - 5385:10,
5632:9
initiate [1] - 5461:19
initiated [29] - 5423:2,
5460:23, 5461:2,
5461:15, 5462:5,
5462:7, 5462:18,
5482:15, 5482:23,
5482:25, 5483:8,
5483:9, 5483:14,
5484:24, 5485:6,
5485:7, 5485:9,
5485:18, 5485:21,
5485:23, 5486:1,
5498:19, 5502:10,
5502:14, 5505:8,
5505:10, 5571:16,
5579:22
initiating [1] - 5479:14
initiation [1] - 5462:19
initiatives [1] -
5470:13
injectable [1] -
5672:22
input [2] - 5697:1,
5701:16
inputs [1] - 5697:2
inquiries [1] - 5682:22
insert [2] - 5679:10,
5679:21
insinuate [1] - 5575:5
instance [4] -
5416:12, 5466:2,
5467:22, 5486:16
instances [1] -
5642:16
instead [5] - 5439:6,
5442:8, 5442:9,
5616:7
instruct [1] - 5421:22
instructed [6] -
5422:18, 5518:21,
5519:9, 5584:3,
5585:16, 5587:6
instruction [5] -

5385:8, 5386:2,
5392:14, 5535:15,
5539:8
instructions [13] -
5384:10, 5384:14,
5384:15, 5384:21,
5384:23, 5385:6,
5385:9, 5385:13,
5385:24, 5386:16,
5386:17, 5386:21,
5538:20
Insurance [1] -
5406:21
insurance [4] -
5407:1, 5576:23,
5577:10
Intelence [145] -
5410:4, 5412:7,
5415:6, 5415:7,
5415:8, 5415:16,
5419:11, 5419:13,
5419:14, 5419:18,
5419:20, 5420:8,
5420:15, 5422:25,
5423:9, 5425:13,
5425:16, 5426:8,
5426:14, 5428:6,
5428:10, 5428:21,
5429:22, 5429:24,
5430:10, 5430:18,
5432:20, 5432:25,
5433:2, 5433:8,
5433:22, 5434:2,
5434:6, 5434:11,
5434:16, 5436:8,
5436:25, 5437:6,
5438:25, 5440:6,
5443:18, 5443:25,
5447:4, 5447:8,
5447:19, 5447:20,
5448:12, 5449:1,
5449:7, 5451:1,
5451:16, 5451:24,
5452:22, 5453:23,
5454:25, 5456:21,
5457:4, 5457:16,
5459:9, 5459:17,
5459:22, 5460:8,
5460:19, 5461:18,
5462:1, 5462:10,
5462:13, 5462:17,
5477:13, 5477:14,
5477:24, 5478:11,
5478:14, 5478:22,
5479:7, 5479:15,
5479:21, 5480:3,
5481:15, 5481:16,
5481:20, 5481:22,
5482:7, 5482:11,
5482:15, 5482:25,
5483:19, 5483:20,

5484:1, 5484:2,
5484:7, 5484:9,
5485:6, 5486:7,
5488:25, 5489:1,
5489:10, 5490:13,
5497:16, 5498:12,
5498:18, 5502:13,
5503:20, 5503:25,
5518:6, 5520:18,
5521:8, 5522:6,
5527:20, 5527:22,
5528:5, 5528:22,
5529:1, 5529:4,
5529:14, 5531:1,
5532:12, 5532:16,
5535:5, 5535:7,
5535:15, 5535:23,
5549:21, 5550:1,
5573:14, 5576:2,
5576:7, 5576:11,
5576:15, 5576:23,
5577:9, 5581:6,
5607:15, 5619:15,
5620:8, 5621:14,
5632:21, 5633:6,
5633:12, 5676:10,
5689:17
intend [8] - 5389:24,
5391:6, 5391:7,
5391:20, 5391:21,
5391:25, 5588:8,
5596:12
intent [1] - 5662:20
interactions [2] -
5655:21, 5661:1
interdisciplinary [1] -
5692:22
interest [4] - 5406:9,
5406:10, 5406:13
interested [5] -
5546:22, 5641:15,
5641:17, 5673:8,
5688:16
interesting [5] -
5425:20, 5477:11,
5556:24, 5578:3,
5590:20
Interestingly [1] -
5477:24
intern [1] - 5654:10
Internal [2] - 5406:2,
5406:4
internal [2] - 5693:22,
5693:23
internally [1] -
5696:25
internationally [2] -
5693:14, 5702:18
interrupting [1] -
5524:20

intervene [1] -
5537:17
interview [1] - 5565:3
interviewed [2] -
5691:25, 5692:1
intimidating [1] -
5435:15
intro [1] - 5397:19
introduce [2] - 5399:3,
5634:4
introducing [1] -
5636:8
intuitive [1] - 5441:24
inverse [1] - 5433:20
inversely [1] - 5443:5
invested [6] - 5441:11,
5473:7, 5473:10,
5473:13, 5474:17,
5474:24
investigation [2] -
5381:9, 5721:5
investigators [1] -
5693:4
investment [11] -
5469:17, 5470:7,
5472:2, 5473:13,
5474:16, 5474:23,
5476:3, 5709:21,
5710:2, 5710:6,
5713:17
invite [1] - 5664:12
invited [3] - 5685:10,
5691:2, 5700:12
inviting [1] - 5699:25
invoicing [1] - 5588:3
involve [2] - 5567:2,
5652:18
involved [17] - 5407:8,
5407:10, 5407:11,
5407:22, 5445:11,
5521:7, 5522:5,
5527:19, 5568:18,
5568:23, 5611:16,
5674:10, 5695:23,
5701:20, 5702:9,
5703:22, 5709:6
involvement [1] -
5641:8
involves [2] - 5528:21,
5708:4
involving [1] - 5407:7
irregular [1] - 5514:24
irrelevant [1] -
5622:20
isolate [2] - 5444:14,
5445:14
ISRAEL [1] - 5379:3
Israel [5] - 5398:12,
5398:14, 5398:18,
5399:5, 5455:13

issue [48] - 5381:22,
5382:1, 5383:10,
5384:4, 5386:11,
5386:14, 5386:15,
5387:12, 5388:22,
5389:5, 5390:15,
5390:18, 5392:10,
5394:18, 5394:20,
5394:21, 5394:23,
5395:3, 5396:6,
5412:21, 5412:24,
5481:6, 5488:8,
5489:18, 5490:12,
5490:13, 5494:14,
5494:19, 5526:6,
5526:7, 5540:18,
5558:6, 5558:15,
5570:10, 5581:20,
5586:1, 5591:6,
5619:20, 5626:14,
5626:17, 5630:21,
5631:5, 5631:9,
5720:13, 5720:19,
5721:1, 5721:5,
5721:7
issues [11] - 5386:8,
5386:25, 5392:12,
5392:15, 5396:9,
5396:10, 5406:20,
5415:21, 5620:21,
5625:23, 5721:3
IT [1] - 5525:25
Item [1] - 5598:14
items [1] - 5556:24
iteration [1] - 5678:3
itself [7] - 5390:21,
5469:12, 5470:18,
5471:8, 5495:23,
5661:24, 5691:13

J

J&J [13] - 5636:11,
5636:14, 5637:4,
5653:12, 5654:4,
5654:10, 5654:15,
5656:20, 5657:17,
5658:1, 5660:19,
5663:11, 5681:15
J&J's [1] - 5653:13
J.P [1] - 5407:20
Janet [4] - 5688:23,
5689:1, 5689:3,
5689:15
Janssen [161] -
5380:18, 5380:20,
5380:21, 5381:2,
5384:7, 5386:12,
5389:2, 5395:9,
5396:3, 5396:15,

5670:18, 5670:19, 5670:21, 5671:12, 5688:14

KIMBERLY [2] - 5379:7, 5670:25

Kimberly [1] - 5671:4

kind [27] - 5386:23, 5387:14, 5392:18, 5393:17, 5435:11, 5441:3, 5442:8, 5444:15, 5450:15, 5474:20, 5487:25, 5533:22, 5540:22, 5561:17, 5630:18, 5640:9, 5641:6, 5674:7, 5684:23, 5689:10, 5693:4, 5693:16, 5694:24, 5698:18, 5702:19, 5703:2, 5704:25

kinds [5] - 5691:19, 5691:20, 5694:21, 5707:25, 5709:8

King [1] - 5378:21

kit [2] - 5717:7, 5717:8

KLEIN [65] - 5378:20, 5379:8, 5380:21, 5670:19, 5671:5, 5677:6, 5677:8, 5677:14, 5677:18, 5677:20, 5678:13, 5678:16, 5681:24, 5682:1, 5682:15, 5682:19, 5682:20, 5685:4, 5685:6, 5686:10, 5686:14, 5686:17, 5686:22, 5687:5, 5687:6, 5687:12, 5687:14, 5688:3, 5688:8, 5692:6, 5692:8, 5695:17, 5695:18, 5696:4, 5696:7, 5699:9, 5699:11, 5702:5, 5702:7, 5704:2, 5704:4, 5705:8, 5705:10, 5705:19, 5705:24, 5706:1, 5706:6, 5706:7, 5710:18, 5710:22, 5712:8, 5712:11, 5712:18, 5712:23, 5713:2, 5713:4, 5715:19, 5715:21, 5716:7, 5716:12, 5717:19, 5717:21, 5719:3, 5719:7, 5719:10

Klein [5] - 5380:21, 5686:8, 5686:21,

5687:2, 5721:24

knowledge [7] - 5492:6, 5492:20, 5493:10, 5493:19, 5494:2, 5604:2, 5680:13

known [2] - 5555:15, 5660:9

knows [1] - 5394:10

Koor [5] - 5401:8, 5401:9, 5401:13, 5401:14

Kubota [2] - 5575:15, 5576:22

L

L.P [1] - 5378:7

label [301] - 5399:20, 5409:3, 5409:4, 5409:8, 5409:17, 5410:7, 5410:9, 5410:14, 5410:16, 5411:20, 5412:6, 5412:13, 5415:22, 5418:17, 5419:12, 5422:22, 5422:23, 5423:1, 5423:4, 5423:7, 5423:8, 5423:14, 5423:19, 5443:9, 5443:11, 5447:4, 5447:8, 5447:17, 5447:18, 5447:21, 5448:1, 5448:4, 5448:7, 5448:9, 5448:12, 5448:19, 5448:25, 5449:7, 5449:16, 5449:18, 5449:22, 5451:1, 5451:7, 5451:9, 5451:12, 5451:16, 5451:23, 5452:1, 5452:4, 5452:22, 5453:4, 5453:5, 5453:24, 5454:25, 5456:6, 5456:7, 5456:9, 5456:21, 5456:25, 5457:1, 5457:4, 5457:16, 5457:22, 5458:6, 5458:10, 5458:19, 5458:22, 5459:25, 5460:1, 5460:4, 5460:8, 5460:14, 5460:18, 5465:3, 5468:19, 5469:2, 5478:21, 5479:12, 5479:13, 5479:15, 5480:25, 5481:2, 5481:11, 5481:16, 5481:20,

5482:4, 5482:5, 5482:6, 5482:10, 5482:14, 5482:24, 5483:1, 5483:2, 5483:25, 5484:1, 5484:8, 5484:18, 5484:23, 5485:5, 5485:12, 5485:13, 5485:15, 5485:16, 5485:17, 5486:6, 5486:12, 5487:20, 5489:10, 5490:8, 5490:11, 5490:19, 5490:25, 5491:6, 5491:8, 5491:13, 5491:15, 5493:14, 5493:15, 5493:16, 5493:22, 5493:23, 5496:5, 5498:24, 5499:4, 5499:5, 5503:6, 5503:11, 5503:13, 5504:1, 5504:23, 5505:14, 5505:18, 5505:25, 5506:1, 5506:2, 5507:16, 5507:20, 5507:25, 5508:1, 5508:9, 5509:3, 5509:6, 5509:12, 5509:17, 5509:23, 5510:5, 5510:10, 5511:13, 5511:15, 5511:21, 5513:6, 5518:3, 5518:17, 5518:20, 5518:22, 5519:8, 5520:17, 5521:7, 5522:5, 5522:25, 5523:20, 5527:19, 5528:5, 5528:12, 5528:21, 5530:11, 5530:23, 5530:25, 5531:18, 5532:20, 5533:4, 5533:9, 5533:14, 5533:22, 5534:2, 5534:20, 5535:5, 5536:7, 5536:9, 5537:8, 5538:8, 5538:21, 5539:9, 5540:7, 5540:14, 5541:1, 5544:22, 5545:9, 5545:11, 5545:12, 5545:24, 5546:11, 5547:8, 5550:8, 5550:13, 5550:14, 5550:15, 5551:14, 5552:10, 5560:6, 5560:10, 5560:21, 5562:7, 5563:16, 5564:9, 5564:11, 5564:15,

5565:19, 5568:17, 5568:23, 5569:1, 5571:16, 5571:20, 5572:7, 5573:2, 5573:3, 5576:16, 5578:6, 5579:22, 5597:21, 5603:20, 5604:10, 5604:20, 5605:16, 5605:22, 5606:16, 5607:8, 5607:14, 5609:6, 5609:16, 5610:3, 5610:7, 5610:16, 5610:18, 5611:7, 5612:16, 5612:22, 5614:6, 5614:14, 5614:23, 5622:16, 5622:23, 5623:3, 5623:5, 5623:11, 5623:13, 5623:15, 5623:18, 5624:25, 5625:6, 5632:22, 5633:13, 5642:1, 5642:8, 5642:19, 5643:12, 5644:8, 5644:19, 5644:24, 5645:4, 5645:5, 5645:8, 5645:12, 5645:22, 5646:1, 5646:6, 5646:21, 5647:16, 5648:20, 5649:9, 5651:23, 5652:19, 5659:12, 5659:25, 5660:9, 5661:4, 5664:2, 5665:16, 5669:7, 5670:6, 5683:2, 5683:15, 5683:17, 5685:8, 5685:10, 5685:12, 5685:17, 5685:25, 5687:8, 5688:17, 5690:12, 5718:19

labeled [1] - 5678:19

labeling [2] - 5678:24, 5685:14

Laboratories [1] - 5672:5

language [2] - 5385:12, 5413:3

large [14] - 5404:5, 5407:20, 5410:21, 5427:21, 5444:9, 5445:17, 5445:22, 5445:24, 5446:4, 5446:5, 5446:10, 5467:16, 5467:17, 5615:10

larger [1] - 5708:1

largest [3] - 5512:13,

5513:1, 5522:19

Largest [1] - 5714:5

last [35] - 5382:2, 5382:13, 5384:21, 5385:18, 5386:8, 5387:8, 5389:10, 5392:4, 5396:15, 5397:10, 5398:17, 5398:19, 5401:25, 5424:9, 5451:2, 5468:3, 5508:22, 5512:23, 5514:5, 5520:24, 5536:2, 5567:1, 5573:12, 5589:5, 5605:6, 5607:2, 5607:24, 5619:7, 5619:11, 5624:5, 5635:25, 5657:16, 5657:20, 5671:3, 5686:16

lasting [2] - 5475:8, 5475:17

late [4] - 5384:22, 5385:20, 5394:6, 5575:16

launch [3] - 5674:3, 5678:4, 5694:4

launched [2] - 5672:11, 5672:19

launching [1] - 5694:8

law [19] - 5420:23, 5421:12, 5421:19, 5421:22, 5421:23, 5421:25, 5422:4, 5422:6, 5422:9, 5422:10, 5422:19, 5445:22, 5445:24, 5446:10, 5593:4, 5594:9, 5594:15, 5629:23

laws [1] - 5675:23

lawsuit [12] - 5532:18, 5535:14, 5541:14, 5563:18, 5578:17, 5581:23, 5582:8, 5591:6, 5606:14, 5611:12, 5659:1, 5659:4

lawyer [3] - 5578:20, 5647:9, 5648:22

Lawyers [1] - 5405:14

lawyers [25] - 5405:16, 5420:21, 5440:2, 5501:25, 5511:8, 5511:11, 5513:7, 5513:9, 5515:10, 5519:9, 5524:10, 5543:22, 5559:13, 5561:11, 5561:18, 5563:17,

5578:17, 5578:22, 5583:1, 5583:4, 5583:19, 5587:11, 5588:9, 5589:18, 5592:17

lay [1] - 5445:25

layers [1] - 5408:18

lead [2] - 5674:12, 5689:7

leadership [1] - 5637:5

leading [1] - 5663:4

learn [2] - 5472:13, 5623:18

learning [1] - 5639:6

least [51] - 5382:21, 5386:13, 5386:19, 5389:23, 5390:22, 5396:5, 5411:14, 5428:12, 5429:6, 5429:7, 5434:5, 5439:10, 5448:4, 5451:18, 5452:6, 5456:2, 5459:9, 5460:23, 5461:12, 5461:20, 5462:16, 5463:7, 5463:8, 5500:8, 5500:11, 5500:12, 5500:13, 5505:11, 5518:12, 5524:3, 5531:22, 5532:12, 5533:9, 5534:1, 5535:22, 5537:9, 5541:1, 5544:17, 5564:25, 5590:14, 5599:18, 5607:17, 5622:5, 5627:7, 5630:11, 5664:21, 5664:25, 5695:22, 5706:3, 5720:7, 5722:7

leave [13] - 5395:12, 5396:9, 5496:25, 5498:6, 5504:3, 5526:2, 5563:15, 5583:5, 5620:20, 5620:25, 5630:14, 5646:14, 5709:18

leaving [1] - 5447:20

lecture [4] - 5478:9, 5478:11, 5717:7, 5717:8

led [1] - 5637:3

left [35] - 5387:15, 5387:18, 5398:3, 5416:8, 5426:2, 5427:20, 5427:21, 5430:20, 5431:6, 5432:18, 5438:13, 5439:12, 5441:24,

5444:10, 5444:20, 5447:23, 5455:5, 5456:8, 5457:24, 5461:10, 5465:22, 5482:4, 5482:5, 5482:14, 5527:6, 5531:23, 5598:14, 5608:19, 5615:1, 5622:17, 5624:25, 5625:5, 5627:22, 5661:3, 5675:14

left-hand [10] - 5426:2, 5430:20, 5431:6, 5439:12, 5441:24, 5444:20, 5447:23, 5461:10, 5482:4, 5482:5

legal [15] - 5393:21, 5409:11, 5418:2, 5420:22, 5426:16, 5488:17, 5561:18, 5582:1, 5596:11, 5596:20, 5629:18, 5679:16, 5694:17, 5695:12, 5705:4

legitimate [1] - 5580:20

less [29] - 5392:22, 5414:23, 5435:17, 5436:25, 5437:14, 5437:18, 5438:1, 5438:7, 5438:9, 5438:20, 5439:1, 5439:6, 5449:15, 5450:17, 5452:13, 5453:15, 5456:8, 5456:14, 5457:7, 5474:20, 5528:5, 5567:25, 5587:18, 5588:23, 5599:6, 5599:7, 5599:19

letter [3] - 5382:10, 5382:13, 5382:17

letters [1] - 5382:6

letting [1] - 5690:7

lettuce [2] - 5446:7, 5446:8

level [5] - 5449:19, 5695:22, 5702:1, 5708:21, 5714:19

levels [3] - 5410:8, 5428:6, 5436:17

leverage [2] - 5404:1, 5408:2

Leveraged [1] - 5405:11

liaison [1] - 5401:15

liaisons [1] - 5709:6

liberty [2] - 5429:12, 5684:14

life [16] - 5420:3, 5444:16, 5445:5, 5458:16, 5469:11, 5469:14, 5471:14, 5471:16, 5517:23, 5552:22, 5594:6, 5595:9, 5595:11, 5596:5, 5630:7, 5633:20

life-extending [1] - 5517:23

lifelong [2] - 5572:25, 5575:9

lifetime [4] - 5628:20, 5629:8, 5630:17, 5630:18

lift [11] - 5471:3, 5471:7, 5473:12, 5473:16, 5473:19, 5474:15, 5476:2, 5476:4, 5477:6, 5477:25

light [1] - 5706:20

likelihood [3] - 5456:20, 5458:15, 5621:22

likely [15] - 5430:18, 5436:7, 5447:3, 5450:25, 5457:15, 5460:7, 5473:2, 5476:24, 5587:1, 5642:15, 5664:10, 5664:14, 5664:18, 5693:16, 5709:5

limine [1] - 5393:14

limit [2] - 5427:11, 5518:14

limitation [1] - 5718:16

limited [3] - 5599:16, 5606:4, 5674:18

line [6] - 5412:9, 5559:13, 5605:4, 5631:2, 5650:9, 5722:9

Line [1] - 5598:14

lines [7] - 5403:23, 5404:12, 5455:3, 5528:10, 5528:13, 5548:13, 5548:20

Link [2] - 5689:3, 5690:20

link [5] - 5581:2, 5581:10, 5709:10, 5713:11, 5714:1

linked [1] - 5440:5

lipid [30] - 5412:25, 5413:6, 5413:7, 5413:20, 5417:22, 5417:23, 5418:4,

5418:8, 5418:9, 5481:5, 5486:4, 5487:19, 5488:8, 5489:18, 5490:12, 5509:22, 5510:4, 5510:11, 5511:12, 5512:12, 5512:23, 5513:2, 5513:5, 5513:6, 5536:4, 5536:12, 5537:2, 5608:18, 5619:20

lipid-regulating [1] - 5417:22

lipid-related [4] - 5417:23, 5418:4, 5418:8, 5418:9

lipids [7] - 5413:13, 5417:20, 5487:24, 5502:12, 5503:17, 5512:19

list [12] - 5443:17, 5550:6, 5567:6, 5615:4, 5624:20, 5692:21, 5701:17, 5701:25, 5702:2, 5702:3, 5702:4, 5703:15

listed [3] - 5415:3, 5534:21, 5592:18

listen [7] - 5653:18, 5655:9, 5657:9, 5661:9, 5667:9, 5667:14, 5667:24

listened [7] - 5527:7, 5638:2, 5641:1, 5644:3, 5644:7, 5647:9, 5654:1

listening [1] - 5619:10

listing [2] - 5549:10, 5631:16

lists [6] - 5548:3, 5697:4, 5697:9, 5702:10, 5710:24

LISTSERVS [1] - 5682:5

litigate [1] - 5618:17

litigation [7] - 5407:8, 5407:11, 5471:13, 5561:24, 5616:15, 5617:19, 5618:9

litigations [1] - 5405:23

live [7] - 5615:13, 5617:3, 5636:13, 5701:19, 5704:14, 5704:15, 5704:17

living [6] - 5558:24, 5673:6, 5674:6, 5676:22, 5707:23, 5709:10

LLP [1] - 5378:19

loading [1] - 5558:8

loathe [1] - 5620:25

located [1] - 5516:5

log [5] - 5381:7, 5383:17, 5383:18, 5563:4, 5690:5

logistically [2] - 5388:10, 5689:5

look [127] - 5382:15, 5394:25, 5395:8, 5408:13, 5413:12, 5414:10, 5414:18, 5415:5, 5419:13, 5423:23, 5424:5, 5424:11, 5424:17, 5425:18, 5428:5, 5428:14, 5430:16, 5433:18, 5435:10, 5435:13, 5436:16, 5436:17, 5437:8, 5437:16, 5438:5, 5438:24, 5439:3, 5443:11, 5443:15, 5446:22, 5447:13, 5447:18, 5448:5, 5451:5, 5451:21, 5452:7, 5452:18, 5453:20, 5454:7, 5458:21, 5462:10, 5462:16, 5463:9, 5465:19, 5466:19, 5467:1, 5468:12, 5469:5, 5469:12, 5470:5, 5470:17, 5471:24, 5475:2, 5479:18, 5491:5, 5496:1, 5496:18, 5505:22, 5506:5, 5506:10, 5506:16, 5506:23, 5507:9, 5512:25, 5517:15, 5528:1, 5535:12, 5543:9, 5544:3, 5547:12, 5548:12, 5548:25, 5552:24, 5560:15, 5562:5, 5562:14, 5562:24, 5563:11, 5563:22, 5565:12, 5566:20, 5567:21, 5567:25, 5570:5, 5571:9, 5571:24, 5575:13, 5582:4, 5590:21, 5597:2, 5598:13, 5602:21, 5607:1, 5611:17, 5612:10, 5613:19, 5615:2, 5615:15, 5623:1, 5623:17, 5626:5,

5627:19, 5628:9,
5630:22, 5661:9,
5664:16, 5664:20,
5667:14, 5680:3,
5686:7, 5688:21,
5692:25, 5695:11,
5698:6, 5698:18,
5703:4, 5706:11,
5707:25, 5712:7,
5714:1, 5715:14,
5721:20
looked [24] - 5381:17,
5433:19, 5434:21,
5459:16, 5471:25,
5517:12, 5539:15,
5543:14, 5544:14,
5554:6, 5560:16,
5562:8, 5563:24,
5567:2, 5572:21,
5602:18, 5604:2,
5620:1, 5623:5,
5624:5, 5664:19,
5684:1, 5700:5,
5717:14
looking [19] - 5432:18,
5433:19, 5442:7,
5449:4, 5473:1,
5482:3, 5483:6,
5487:9, 5548:23,
5556:8, 5572:11,
5576:5, 5591:8,
5597:7, 5597:10,
5613:8, 5674:4,
5676:24, 5706:12
looks [7] - 5409:21,
5430:5, 5682:4,
5685:16, 5695:25,
5712:12, 5716:1
losing [1] - 5696:6
lost [5] - 5403:24,
5414:23, 5615:16,
5627:12, 5628:5
lottery [6] - 5435:22,
5436:1, 5436:2,
5450:20
lousy [1] - 5616:11
love [3] - 5431:22,
5431:23, 5441:25
low [3] - 5431:21,
5435:21, 5452:13
lower [4] - 5427:24,
5496:11, 5496:13,
5627:13
loyalty [2] - 5478:5,
5478:7
Loyalty [6] - 5469:19,
5470:6, 5472:5,
5475:2, 5476:8,
5477:12
luck [2] - 5443:2,

5449:25
lucky [2] - 5595:2,
5615:21
lump [2] - 5580:23,
5626:22
lump-sum [1] -
5580:23
lunch [13] - 5383:24,
5384:2, 5496:16,
5525:16, 5525:17,
5526:9, 5526:14,
5526:15, 5558:1,
5558:4, 5559:10,
5559:17, 5690:25
Luncheon [1] - 5559:4
lunches [1] - 5558:9
luxury [2] - 5420:3,
5626:6
lying [2] - 5663:22,
5663:24

M

M-C-G-R-A-T-H [1] -
5636:1
ma'am [23] - 5637:11,
5638:12, 5638:21,
5639:3, 5640:6,
5640:19, 5643:5,
5643:23, 5644:4,
5644:11, 5644:22,
5645:3, 5645:7,
5645:20, 5647:3,
5647:7, 5648:9,
5649:3, 5652:2,
5652:11, 5656:11,
5660:14, 5669:4
Madness [1] - 5404:20
magnet [1] - 5522:3
mailroom [1] - 5405:6
main [3] - 5404:12,
5407:17, 5704:19
maintain [1] - 5395:3
maintained [1] -
5704:8
majority [7] - 5408:4,
5441:15, 5448:21,
5452:6, 5456:1,
5456:12, 5605:23
manage [1] - 5501:19
managed [2] -
5666:18, 5689:8
management [5] -
5472:12, 5472:19,
5659:20, 5692:1,
5700:13
manager [14] - 5640:7,
5641:2, 5641:19,
5655:6, 5655:11,
5666:22, 5667:13,

5668:6, 5673:23,
5673:24, 5674:12,
5701:15, 5702:2
manager's [2] -
5641:19, 5642:13
managers [4] -
5606:7, 5641:19,
5682:7, 5701:14
managing [3] -
5690:3, 5693:18,
5707:23
mandate [1] - 5705:4
manner [1] - 5717:25
manufactured [1] -
5394:23
manufacturer [1] -
5401:12
mapping [1] - 5695:21
March [2] - 5471:19,
5675:15
margins [1] - 5462:3
Mark [3] - 5539:2,
5539:12, 5567:7
market [20] - 5400:9,
5414:11, 5414:15,
5414:16, 5414:17,
5414:20, 5415:1,
5415:17, 5481:17,
5674:2, 5674:4,
5674:7, 5692:11,
5692:19, 5693:11,
5696:24, 5702:14,
5717:22, 5717:24
marketed [1] - 5597:8
marketer [1] - 5713:14
Marketing [6] -
5469:19, 5470:6,
5472:6, 5475:3,
5476:8, 5477:12
marketing [99] -
5399:15, 5399:20,
5409:3, 5409:4,
5410:7, 5410:14,
5412:6, 5412:13,
5415:22, 5416:20,
5416:21, 5422:22,
5422:23, 5423:7,
5423:10, 5423:17,
5445:14, 5446:17,
5446:24, 5447:11,
5448:11, 5449:5,
5453:21, 5453:22,
5454:24, 5457:3,
5458:5, 5463:10,
5464:19, 5465:15,
5465:21, 5466:4,
5466:9, 5467:1,
5468:14, 5468:22,
5469:17, 5469:22,
5469:23, 5470:6,

5470:7, 5470:12,
5472:7, 5472:15,
5472:25, 5478:21,
5479:12, 5479:13,
5481:3, 5595:25,
5598:8, 5598:13,
5598:14, 5599:15,
5599:23, 5600:5,
5600:12, 5600:13,
5600:16, 5600:19,
5601:7, 5601:8,
5601:11, 5601:14,
5601:19, 5602:16,
5616:3, 5623:3,
5631:25, 5632:20,
5633:10, 5633:11,
5649:9, 5651:23,
5652:19, 5659:12,
5659:25, 5660:9,
5661:5, 5664:2,
5665:16, 5670:6,
5671:20, 5671:21,
5672:18, 5679:16,
5681:20, 5691:16,
5692:22, 5693:25,
5696:13, 5698:6,
5698:9, 5700:13,
5701:13, 5702:15,
5704:9
Marketos [23] -
5380:10, 5382:20,
5385:23, 5389:19,
5390:17, 5391:4,
5394:8, 5395:15,
5396:20, 5397:17,
5398:8, 5398:22,
5422:3, 5463:13,
5463:22, 5464:4,
5494:7, 5494:20,
5547:14, 5593:11,
5594:15, 5629:5,
5633:22
MARKETOS [104] -
5378:14, 5378:14,
5379:4, 5379:5,
5380:9, 5382:24,
5383:1, 5385:25,
5386:3, 5386:7,
5386:10, 5387:2,
5387:6, 5387:11,
5387:20, 5388:4,
5388:12, 5388:15,
5388:21, 5389:1,
5390:18, 5391:12,
5394:10, 5394:17,
5395:23, 5396:1,
5396:23, 5397:1,
5397:12, 5397:19,
5398:10, 5398:24,
5398:25, 5421:4,
5421:9, 5422:12,

5422:16, 5463:15,
5463:23, 5464:10,
5464:11, 5494:6,
5495:11, 5495:16,
5495:25, 5496:11,
5496:13, 5496:18,
5496:23, 5517:5,
5524:20, 5525:1,
5525:12, 5526:7,
5526:9, 5526:12,
5526:17, 5547:15,
5547:18, 5583:22,
5585:3, 5585:24,
5586:5, 5586:13,
5593:12, 5593:18,
5593:20, 5593:23,
5594:1, 5594:3,
5596:24, 5597:1,
5611:18, 5611:23,
5612:10, 5612:12,
5613:5, 5613:6,
5617:6, 5617:13,
5617:16, 5617:21,
5617:25, 5618:3,
5618:10, 5618:20,
5618:22, 5618:24,
5619:3, 5619:12,
5620:13, 5620:15,
5628:9, 5628:11,
5629:6, 5629:7,
5633:15, 5633:23,
5634:4, 5634:7,
5634:9, 5720:4,
5720:14, 5722:13
Marsh [4] - 5687:24,
5688:15, 5689:16,
5689:21
Marshal [4] - 5525:9,
5558:14, 5558:17,
5558:20
Marshals [1] - 5525:4
marshals [3] -
5525:14, 5525:22,
5526:15
master [2] - 5402:18,
5702:3
master's [3] - 5399:24,
5400:25, 5401:4
match [1] - 5615:5
matched [1] - 5614:16
matching [2] -
5624:22, 5624:24
materials [6] -
5679:23, 5680:14,
5680:20, 5680:22,
5680:25, 5689:25
math [3] - 5438:19,
5534:23, 5572:15
mathematical [3] -
5431:1, 5533:19,

5615:12
mathematically [1] - 5488:22
Matt [1] - 5537:24
matter [13] - 5386:2, 5421:7, 5499:3, 5544:21, 5560:9, 5576:1, 5576:10, 5592:12, 5603:24, 5633:2, 5633:3, 5723:5
matters [2] - 5407:3, 5499:14
Mattes [2] - 5610:22, 5628:15
Matthews [1] - 5614:13
MBA [6] - 5401:6, 5401:17, 5401:18, 5637:2, 5640:22, 5640:23
McElfresh [1] - 5550:2
MCGRATH [2] - 5379:5, 5635:22
McGrath [32] - 5635:5, 5635:19, 5636:1, 5636:5, 5636:11, 5636:19, 5637:22, 5638:20, 5639:23, 5640:9, 5641:23, 5643:4, 5643:23, 5648:5, 5648:18, 5648:23, 5649:7, 5649:11, 5652:21, 5653:3, 5656:16, 5658:4, 5661:18, 5663:8, 5665:7, 5667:10, 5667:24, 5668:13, 5668:19, 5668:24, 5670:4, 5670:10
McKay [2] - 5378:23, 5723:11
McKay-Soule [2] - 5378:23, 5723:11
MEAGHER [1] - 5378:19
meal [1] - 5674:21
meals [1] - 5689:9
mean [53] - 5381:17, 5382:4, 5388:23, 5390:24, 5392:5, 5392:7, 5394:2, 5394:5, 5395:9, 5414:23, 5419:5, 5422:8, 5422:9, 5432:23, 5438:4, 5441:25, 5446:4, 5447:21, 5448:3, 5455:12, 5456:9,

5456:16, 5471:4, 5490:10, 5495:16, 5495:17, 5495:22, 5496:14, 5503:6, 5526:21, 5557:8, 5557:11, 5557:15, 5568:22, 5570:4, 5585:17, 5589:16, 5609:23, 5617:19, 5617:20, 5664:10, 5675:6, 5675:12, 5679:8, 5695:21, 5700:4, 5703:13, 5706:20, 5707:13, 5707:21, 5709:13, 5711:4
meaning [4] - 5584:15, 5610:5, 5657:23, 5713:24
means [38] - 5409:10, 5414:17, 5414:23, 5423:2, 5423:3, 5434:7, 5436:4, 5439:23, 5442:13, 5442:17, 5442:20, 5443:4, 5445:23, 5446:1, 5447:16, 5447:24, 5448:4, 5448:6, 5450:12, 5451:19, 5458:14, 5460:3, 5461:13, 5478:11, 5490:17, 5491:12, 5502:4, 5502:5, 5505:3, 5542:7, 5549:15, 5569:6, 5569:9, 5570:1, 5570:4, 5679:5
Means [1] - 5406:1
meant [5] - 5382:9, 5565:24, 5575:22, 5576:21, 5589:17
measure [7] - 5431:8, 5431:10, 5435:16, 5623:10, 5623:15, 5710:2, 5710:4
mechanical [1] - 5378:25
mechanisms [1] - 5681:17
MedEd [2] - 5689:3, 5690:20
MedEd-Link [2] - 5689:3, 5690:20
Media [1] - 5689:6
median [38] - 5430:21, 5431:6, 5431:10, 5431:12, 5431:20, 5431:21, 5432:19, 5433:9, 5434:4,

5434:7, 5435:7, 5438:13, 5446:3, 5447:8, 5447:23, 5448:3, 5448:6, 5448:14, 5448:16, 5450:5, 5451:12, 5451:19, 5451:22, 5452:1, 5453:3, 5455:6, 5456:6, 5457:18, 5457:22, 5457:24, 5467:1, 5467:3, 5467:4, 5557:7, 5557:9, 5602:7, 5602:11
Medicaid [28] - 5427:3, 5427:5, 5427:7, 5427:11, 5427:14, 5480:1, 5485:5, 5486:4, 5579:12, 5579:18, 5582:5, 5582:14, 5582:19, 5614:24, 5624:20, 5624:23, 5625:11, 5626:21, 5627:8, 5627:9, 5627:10, 5627:13, 5627:15, 5627:20, 5627:23, 5628:6
medical [17] - 5409:11, 5418:2, 5489:16, 5509:17, 5522:18, 5523:14, 5566:14, 5574:3, 5646:14, 5666:17, 5676:1, 5692:23, 5695:11, 5697:11, 5698:11, 5704:22
medically [3] - 5509:7, 5510:23, 5620:2
Medicare [11] - 5427:10, 5427:19, 5480:1, 5485:5, 5486:4, 5577:3, 5579:17, 5624:21, 5625:10, 5626:21
medication [5] - 5417:22, 5418:9, 5418:19, 5418:25, 5419:16
medicine [15] - 5418:4, 5429:7, 5510:10, 5516:12, 5542:24, 5547:8, 5550:20, 5551:3, 5551:14, 5570:21, 5571:5, 5576:15, 5576:22, 5581:6, 5676:11
medicines [15] - 5497:21, 5498:2,

5503:2, 5504:23, 5509:12, 5516:20, 5518:6, 5518:7, 5518:14, 5518:22, 5527:12, 5576:14, 5577:4, 5577:18, 5582:6
medium [2] - 5439:9
meet [7] - 5486:23, 5569:9, 5653:10, 5653:15, 5662:4, 5684:20, 5720:11
meeting [41] - 5563:10, 5564:12, 5638:2, 5638:4, 5638:11, 5639:2, 5639:10, 5640:17, 5641:9, 5641:23, 5642:3, 5644:3, 5645:10, 5645:11, 5645:16, 5645:21, 5645:25, 5646:4, 5646:14, 5646:18, 5647:8, 5647:10, 5647:11, 5647:19, 5656:3, 5658:17, 5660:7, 5661:21, 5661:22, 5661:23, 5661:25, 5662:19, 5663:5, 5664:9, 5664:12, 5664:22, 5691:9, 5700:1, 5704:16, 5704:17
meetings [6] - 5637:22, 5658:6, 5664:11, 5689:5, 5689:19, 5690:21
Megan [6] - 5378:23, 5635:5, 5635:19, 5636:1, 5636:11, 5723:11
MEGAN [2] - 5379:5, 5635:22
Megan_McKay [1] - 5378:24
Megan_McKay-Soule@njd. uscourts.gov [1] - 5378:24
Member [1] - 5406:23
member [1] - 5699:15
members [20] - 5397:25, 5399:3, 5399:13, 5399:17, 5412:18, 5413:16, 5415:15, 5424:3, 5427:24, 5437:3, 5447:7, 5462:22, 5481:2, 5482:20, 5488:21, 5603:9,

5610:15, 5611:22, 5620:1, 5695:11
memories [1] - 5663:14
memory [11] - 5535:23, 5536:3, 5537:2, 5538:10, 5638:4, 5639:23, 5640:15, 5658:20, 5663:9, 5663:10
mention [4] - 5542:24, 5646:21, 5708:19, 5708:20
mentioned [11] - 5445:16, 5475:9, 5482:1, 5585:23, 5624:19, 5625:25, 5630:5, 5690:15, 5690:18, 5696:24, 5707:19
mentorship [1] - 5637:19
menu [1] - 5690:24
merely [1] - 5517:19
mergers [3] - 5403:25, 5404:4, 5404:9
message [33] - 5423:18, 5520:17, 5521:7, 5527:19, 5527:22, 5528:5, 5528:6, 5529:14, 5531:1, 5532:20, 5533:4, 5533:14, 5533:22, 5534:20, 5536:3, 5538:2, 5538:16, 5545:11, 5545:13, 5546:4, 5547:1, 5550:13, 5563:9, 5567:9, 5567:14, 5603:20, 5604:10, 5604:20, 5606:8, 5606:19, 5607:5, 5607:19, 5607:20
messages [27] - 5416:23, 5444:4, 5511:8, 5522:5, 5528:21, 5530:3, 5530:6, 5530:11, 5530:17, 5530:21, 5530:24, 5531:5, 5531:11, 5531:18, 5532:12, 5533:9, 5534:2, 5535:20, 5536:9, 5537:8, 5538:9, 5541:1, 5545:24, 5550:14, 5607:15, 5608:1, 5609:16
met [9] - 5487:5,

5383:1, 5383:12, 5383:18, 5383:21, 5384:1, 5384:18, 5385:1, 5385:10, 5385:16, 5385:20, 5385:22, 5385:25, 5386:3, 5386:7, 5386:10, 5387:2, 5387:6, 5387:11, 5387:20, 5388:4, 5388:12, 5388:15, 5388:21, 5389:1, 5389:4, 5390:12, 5390:18, 5391:12, 5391:23, 5392:3, 5392:9, 5392:21, 5393:1, 5393:4, 5393:15, 5393:25, 5394:5, 5394:10, 5394:17, 5395:23, 5396:1, 5396:13, 5396:17, 5396:23, 5397:1, 5397:12, 5397:13, 5397:19, 5398:10, 5398:24, 5398:25, 5421:4, 5421:9, 5422:12, 5422:16, 5463:15, 5463:23, 5464:10, 5464:11, 5494:6, 5495:11, 5495:16, 5495:23, 5495:25, 5496:11, 5496:13, 5496:18, 5496:23, 5517:5, 5524:20, 5525:1, 5525:12, 5526:7, 5526:9, 5526:12, 5526:17, 5547:15, 5547:18, 5583:22, 5585:3, 5585:24, 5586:5, 5586:13, 5593:12, 5593:18, 5593:20, 5593:23, 5594:1, 5594:3, 5596:24, 5597:1, 5611:18, 5611:23, 5612:10, 5612:12, 5613:5, 5613:6, 5617:6, 5617:13, 5617:16, 5617:21, 5617:25, 5618:3, 5618:10, 5618:20, 5618:22, 5618:24, 5619:3, 5619:12, 5620:13, 5620:15, 5628:9, 5628:11, 5629:6, 5629:7, 5633:15, 5633:23, 5634:4, 5634:7, 5634:9, 5634:16, 5649:19,

5649:23, 5650:5, 5650:16, 5650:25, 5651:2, 5651:7, 5653:1, 5653:2, 5661:9, 5661:11, 5661:17, 5667:16, 5668:7, 5670:19, 5671:5, 5677:6, 5677:8, 5677:14, 5677:15, 5677:18, 5677:20, 5678:13, 5678:16, 5681:24, 5682:1, 5682:15, 5682:16, 5682:19, 5682:20, 5685:4, 5685:6, 5686:10, 5686:14, 5686:17, 5686:22, 5687:5, 5687:6, 5687:12, 5687:14, 5688:3, 5688:5, 5688:8, 5692:6, 5692:8, 5695:17, 5695:18, 5696:4, 5696:7, 5699:9, 5699:11, 5702:5, 5702:7, 5704:2, 5704:4, 5705:8, 5705:10, 5705:19, 5705:21, 5705:24, 5706:1, 5706:6, 5706:7, 5710:18, 5710:22, 5712:8, 5712:11, 5712:18, 5712:20, 5712:23, 5713:2, 5713:4, 5715:19, 5715:21, 5716:7, 5716:9, 5716:12, 5717:19, 5717:21, 5719:3, 5719:7, 5719:10, 5720:4, 5720:14, 5722:13
MS [119] - 5379:4, 5379:6, 5379:7, 5380:11, 5380:17, 5384:12, 5397:4, 5397:14, 5421:1, 5421:5, 5421:14, 5421:19, 5422:8, 5494:9, 5494:13, 5494:17, 5494:19, 5494:21, 5495:2, 5495:5, 5495:10, 5495:14, 5495:21, 5496:10, 5496:12, 5496:14, 5497:4, 5497:8, 5497:10, 5497:11, 5498:8, 5498:9, 5499:22, 5499:25, 5507:1, 5507:4, 5507:5,

5517:3, 5517:8, 5521:16, 5521:18, 5526:20, 5526:24, 5527:3, 5527:5, 5537:23, 5547:14, 5547:16, 5547:19, 5547:22, 5547:24, 5548:17, 5548:22, 5557:24, 5558:2, 5559:19, 5559:21, 5571:10, 5571:12, 5574:9, 5574:10, 5584:2, 5584:5, 5584:10, 5584:13, 5584:17, 5584:19, 5585:14, 5586:12, 5586:16, 5586:18, 5593:7, 5593:14, 5593:17, 5593:19, 5613:3, 5616:18, 5616:20, 5617:1, 5617:5, 5617:10, 5618:6, 5629:2, 5634:14, 5635:3, 5635:5, 5635:9, 5635:12, 5635:18, 5636:3, 5636:4, 5638:15, 5638:19, 5639:19, 5639:22, 5643:2, 5643:3, 5650:8, 5650:12, 5650:14, 5650:22, 5651:15, 5651:17, 5668:10, 5668:12, 5668:16, 5668:18, 5668:25, 5669:1, 5670:8, 5670:13, 5670:17, 5720:5, 5720:16, 5721:14, 5721:22, 5722:6, 5722:10, 5722:16
multidisciplinary [2] - 5679:13, 5693:24
multimillion [1] - 5435:22
multiple [8] - 5476:21, 5530:3, 5530:6, 5530:11, 5649:2, 5662:2, 5662:4, 5662:5
multiply [2] - 5474:10, 5625:2
Murphy [2] - 5609:7, 5660:2
must [13] - 5455:11, 5606:22, 5678:23, 5685:8, 5685:13, 5696:12, 5696:15, 5699:14, 5699:16, 5700:13, 5704:6,

5704:8, 5716:20
mutually [1] - 5711:15

N

naive [32] - 5412:19, 5413:4, 5415:8, 5415:14, 5418:15, 5419:13, 5419:15, 5455:13, 5481:11, 5481:12, 5481:15, 5481:17, 5481:20, 5486:5, 5486:11, 5486:20, 5486:22, 5487:18, 5487:25, 5488:9, 5489:1, 5502:13, 5503:17, 5503:20, 5535:6, 5535:8, 5535:15, 5535:19, 5535:23, 5538:2, 5538:9
name [20] - 5398:16, 5398:17, 5398:20, 5399:5, 5401:13, 5404:19, 5407:16, 5542:24, 5635:24, 5635:25, 5653:5, 5660:5, 5660:7, 5660:24, 5660:25, 5661:1, 5671:2, 5671:3, 5671:12, 5692:25
named [2] - 5673:10, 5716:3
names [1] - 5624:3
Nancy [3] - 5606:15, 5609:8, 5660:4
narrow [1] - 5486:17
nation [3] - 5429:17, 5461:23, 5631:1
national [9] - 5516:19, 5516:23, 5517:1, 5517:10, 5615:6, 5622:12, 5622:19, 5631:16, 5682:11
National [2] - 5517:15, 5517:17
nationally [2] - 5682:8, 5682:9
nationwide [2] - 5578:8, 5606:6
naturally [1] - 5561:2
nature [3] - 5544:24, 5627:15, 5627:24
NBA [1] - 5432:7
near [1] - 5558:8
nearly [5] - 5415:19, 5541:14, 5547:6, 5550:6, 5564:21
necessarily [5] -

5391:17, 5392:7, 5531:21, 5546:16, 5632:15
necessary [4] - 5389:15, 5393:6, 5615:1, 5623:2
need [33] - 5381:25, 5383:1, 5383:5, 5383:7, 5383:19, 5386:2, 5386:25, 5389:3, 5392:8, 5394:9, 5394:15, 5396:6, 5396:25, 5397:9, 5438:19, 5455:4, 5458:13, 5496:18, 5506:21, 5516:20, 5524:22, 5525:22, 5537:19, 5603:16, 5626:9, 5644:12, 5719:23, 5719:25, 5720:1, 5720:2, 5720:21, 5721:17, 5722:8
needed [6] - 5383:9, 5385:16, 5385:17, 5419:9, 5567:8, 5590:7
needs [10] - 5574:18, 5585:6, 5634:14, 5692:2, 5694:9, 5694:12, 5694:22, 5695:3, 5696:22, 5720:11
negates [1] - 5475:9
negative [1] - 5443:4
neighborhood [5] - 5431:14, 5431:15, 5431:16, 5431:17
nervous [4] - 5577:21, 5578:2, 5647:20, 5647:21
net [2] - 5473:12, 5474:15
neutral [1] - 5536:12
never [40] - 5405:17, 5409:11, 5415:10, 5415:13, 5423:16, 5423:17, 5423:18, 5434:5, 5434:16, 5481:20, 5481:21, 5481:24, 5482:2, 5503:24, 5535:6, 5535:7, 5535:16, 5539:7, 5540:18, 5540:21, 5540:22, 5544:14, 5561:12, 5568:9, 5572:21, 5577:1, 5577:8, 5583:16, 5592:25, 5619:22, 5629:19,

5423:4, 5423:7,
5423:8, 5423:14,
5423:19, 5443:9,
5443:11, 5447:8,
5447:17, 5447:18,
5447:21, 5448:1,
5448:4, 5448:7,
5448:19, 5448:25,
5449:16, 5449:18,
5451:9, 5451:16,
5451:23, 5452:1,
5452:4, 5453:4,
5453:5, 5454:25,
5456:6, 5456:7,
5456:9, 5457:4,
5457:22, 5458:6,
5458:10, 5458:19,
5458:22, 5459:25,
5460:1, 5460:4,
5460:8, 5460:14,
5460:18, 5465:3,
5468:19, 5469:2,
5478:21, 5479:12,
5479:13, 5479:15,
5480:25, 5481:2,
5482:4, 5482:5,
5482:6, 5482:10,
5482:14, 5482:24,
5483:1, 5483:2,
5483:25, 5484:1,
5484:18, 5484:23,
5485:5, 5485:12,
5485:13, 5485:15,
5485:16, 5485:17,
5486:6, 5486:12,
5487:20, 5489:10,
5490:8, 5490:11,
5490:19, 5490:25,
5491:6, 5491:8,
5491:13, 5491:15,
5493:14, 5493:15,
5493:16, 5493:22,
5493:23, 5496:5,
5498:24, 5503:6,
5503:11, 5503:13,
5504:1, 5504:23,
5505:14, 5505:18,
5505:25, 5506:1,
5506:2, 5507:16,
5507:20, 5507:25,
5508:1, 5508:9,
5509:3, 5509:6,
5509:12, 5509:17,
5509:23, 5510:5,
5511:13, 5511:15,
5511:21, 5513:6,
5518:3, 5518:17,
5518:20, 5518:22,
5519:8, 5520:17,
5521:7, 5522:5,
5527:19, 5528:5,

5528:12, 5528:21,
5530:11, 5530:23,
5530:25, 5531:18,
5532:20, 5533:4,
5533:9, 5533:14,
5533:22, 5534:2,
5534:20, 5535:5,
5536:7, 5536:9,
5537:8, 5538:8,
5540:14, 5541:1,
5544:22, 5545:9,
5545:11, 5545:12,
5545:24, 5546:11,
5547:8, 5550:8,
5550:13, 5550:14,
5550:15, 5551:14,
5552:10, 5560:6,
5560:10, 5560:21,
5562:7, 5563:16,
5564:15, 5565:19,
5568:23, 5569:1,
5571:20, 5572:7,
5573:2, 5578:6,
5579:22, 5597:21,
5603:20, 5604:10,
5604:20, 5605:16,
5607:8, 5607:14,
5609:16, 5610:3,
5610:18, 5611:7,
5612:22, 5614:14,
5614:23, 5622:16,
5622:23, 5623:3,
5623:5, 5623:11,
5623:13, 5623:15,
5623:18, 5624:25,
5625:6, 5632:22,
5633:13, 5642:8,
5642:19, 5643:12,
5644:8, 5644:19,
5644:24, 5645:4,
5645:5, 5645:8,
5645:12, 5645:22,
5646:1, 5646:6,
5646:21, 5647:16,
5648:20, 5649:9,
5651:23, 5652:19,
5659:12, 5659:25,
5660:9, 5661:4,
5664:2, 5665:16,
5669:7, 5670:6,
5683:2, 5683:15,
5683:17, 5685:10,
5685:12, 5690:12
off-line [1] - 5559:13
offended [2] - 5574:8,
5574:11
offensive [2] -
5574:17, 5575:6
offer [1] - 5515:1
offered [1] - 5671:20

offering [2] - 5464:14,
5515:25
office [11] - 5532:24,
5540:7, 5540:13,
5642:14, 5662:1,
5662:17, 5662:21,
5664:7, 5666:2,
5701:13, 5702:4
officer [1] - 5642:15
official [1] - 5645:22
OFFICIAL [1] - 5723:1
Official [1] - 5378:23
offset [2] - 5586:1,
5586:7
often [6] - 5595:24,
5684:10, 5692:23,
5701:3, 5706:25,
5707:2
oftentimes [1] -
5704:14
old [2] - 5407:16,
5673:4
on-label [3] - 5544:22,
5565:19, 5573:3
once [38] - 5392:15,
5394:14, 5395:14,
5415:11, 5415:13,
5419:18, 5419:21,
5420:7, 5426:16,
5438:8, 5455:25,
5479:19, 5481:22,
5481:24, 5488:25,
5490:7, 5490:13,
5499:8, 5503:20,
5529:4, 5560:4,
5560:20, 5561:4,
5564:5, 5566:17,
5575:21, 5577:16,
5580:18, 5594:6,
5606:12, 5608:3,
5630:5, 5630:16,
5660:7, 5660:25,
5661:24, 5680:5
once-a-day [1] -
5608:3
once-daily [8] -
5415:11, 5419:18,
5419:21, 5420:7,
5481:22, 5481:24,
5488:25, 5490:13
one [305] - 5383:12,
5384:4, 5386:4,
5387:4, 5388:13,
5389:4, 5390:4,
5390:5, 5393:2,
5395:1, 5398:3,
5398:5, 5400:17,
5400:20, 5401:9,
5401:15, 5404:12,
5405:7, 5406:11,

5408:19, 5409:3,
5409:7, 5411:2,
5412:8, 5412:9,
5412:10, 5413:6,
5414:20, 5416:6,
5416:8, 5417:3,
5418:21, 5419:25,
5423:5, 5423:9,
5425:16, 5425:23,
5427:6, 5428:12,
5429:4, 5429:6,
5429:7, 5430:16,
5431:14, 5431:15,
5432:2, 5432:15,
5433:2, 5433:4,
5433:7, 5434:3,
5434:15, 5435:10,
5437:7, 5437:11,
5437:19, 5437:20,
5437:21, 5437:25,
5438:1, 5438:3,
5438:7, 5438:20,
5439:8, 5439:9,
5439:12, 5439:18,
5439:19, 5439:20,
5443:2, 5443:3,
5443:17, 5444:10,
5444:11, 5444:15,
5444:25, 5445:7,
5446:7, 5446:8,
5446:17, 5448:8,
5448:24, 5448:25,
5449:2, 5450:18,
5450:19, 5450:21,
5451:2, 5451:25,
5452:3, 5452:25,
5453:5, 5453:15,
5455:2, 5455:21,
5456:5, 5456:6,
5457:24, 5459:9,
5460:4, 5460:23,
5461:12, 5461:13,
5461:17, 5461:20,
5461:21, 5462:5,
5462:17, 5466:4,
5466:6, 5466:11,
5470:17, 5471:18,
5471:19, 5472:19,
5473:13, 5475:11,
5478:5, 5478:13,
5478:15, 5481:5,
5484:20, 5484:21,
5487:16, 5489:15,
5490:11, 5493:5,
5494:14, 5494:19,
5500:8, 5500:9,
5500:13, 5501:3,
5502:25, 5503:25,
5505:10, 5505:12,
5508:4, 5508:7,
5508:16, 5508:22,

5509:20, 5510:16,
5512:15, 5514:25,
5516:10, 5516:14,
5518:2, 5519:19,
5519:25, 5520:4,
5520:16, 5522:13,
5523:11, 5529:1,
5530:12, 5530:14,
5530:17, 5531:12,
5531:16, 5532:12,
5533:17, 5534:1,
5535:4, 5535:5,
5537:9, 5538:8,
5540:21, 5543:7,
5543:12, 5543:18,
5544:10, 5544:12,
5545:10, 5545:22,
5548:1, 5548:24,
5549:5, 5549:9,
5551:3, 5552:12,
5552:15, 5553:6,
5553:11, 5553:14,
5554:16, 5555:7,
5556:3, 5560:4,
5560:9, 5560:18,
5560:19, 5561:21,
5562:13, 5563:3,
5563:9, 5563:10,
5563:20, 5564:2,
5564:4, 5564:20,
5565:7, 5565:14,
5567:1, 5567:17,
5567:22, 5569:4,
5571:20, 5572:4,
5572:22, 5575:16,
5576:14, 5576:21,
5578:12, 5581:19,
5583:17, 5588:2,
5588:3, 5588:18,
5594:14, 5595:23,
5596:23, 5597:2,
5597:3, 5597:10,
5597:15, 5597:16,
5598:14, 5598:24,
5599:1, 5599:10,
5599:15, 5599:23,
5601:19, 5601:22,
5601:23, 5602:12,
5602:20, 5604:3,
5607:10, 5608:3,
5608:8, 5614:1,
5616:4, 5616:13,
5618:3, 5620:10,
5623:1, 5623:6,
5623:10, 5624:5,
5626:10, 5626:22,
5627:17, 5627:19,
5627:23, 5628:5,
5630:5, 5631:17,
5632:23, 5634:2,
5645:3, 5647:10,

5655:16, 5664:21,
5672:3, 5673:3,
5673:4, 5674:3,
5674:22, 5686:11,
5686:12, 5689:16,
5691:16, 5693:1,
5693:12, 5695:7,
5698:22, 5699:13,
5699:24, 5703:3,
5707:6, 5712:14,
5713:3, 5715:9,
5715:15, 5716:1
One [1] - 5378:21
one-hour [1] -
5686:12
one-plus [1] - 5599:23
one-size-fits-all [1] -
5551:3
one-third [4] - 5429:4,
5451:25, 5628:5,
5699:13
ones [9] - 5384:24,
5412:8, 5433:3,
5438:8, 5457:21,
5461:17, 5599:19,
5608:14, 5634:17
online [1] - 5696:25
open [5] - 5380:1,
5383:6, 5387:18,
5389:6, 5653:19
Open [6] - 5422:15,
5497:7, 5527:2,
5586:15, 5619:6,
5651:14
opened [1] - 5494:24
opening [2] - 5495:7,
5662:18
openly [1] - 5515:14
operated [1] - 5568:12
operational [1] -
5401:19
operations [1] -
5390:19
opine [8] - 5408:20,
5424:24, 5428:3,
5475:24, 5514:24,
5516:23, 5582:12,
5632:16
opinion [37] -
5408:16, 5409:2,
5409:11, 5413:8,
5420:4, 5430:17,
5438:4, 5441:25,
5449:10, 5460:11,
5472:20, 5475:13,
5475:22, 5494:22,
5498:17, 5500:3,
5501:11, 5501:14,
5502:5, 5505:21,
5511:3, 5515:1,

5515:25, 5516:8,
5518:10, 5518:20,
5518:24, 5524:11,
5551:22, 5552:6,
5576:11, 5579:4,
5595:1, 5596:19,
5622:20, 5685:22
opinions [6] -
5406:11, 5408:3,
5413:20, 5463:3,
5463:4, 5464:14
opportunities [1] -
5673:9
opportunity [9] -
5387:23, 5391:2,
5393:22, 5396:5,
5405:24, 5593:3,
5608:16, 5653:10,
5675:5
oppose [1] - 5391:5
opposed [5] - 5391:4,
5421:24, 5427:14,
5437:24, 5486:23
opposite [2] -
5441:14, 5528:4
opposition [1] -
5395:25
options [1] - 5674:17
oral [1] - 5390:20
orally [5] - 5389:12,
5390:21, 5393:17,
5395:20
orange [1] - 5425:17
order [19] - 5387:1,
5388:2, 5390:19,
5408:3, 5410:13,
5421:11, 5424:11,
5440:13, 5441:19,
5458:1, 5458:2,
5490:14, 5622:24,
5625:23, 5647:1,
5665:23, 5682:24,
5691:18, 5720:22
ordered [1] - 5525:19
organizations [1] -
5709:8
organize [1] - 5697:5
organized [1] - 5689:5
orientation [1] -
5517:22
original [2] - 5553:17,
5644:20
originally [3] - 5594:9,
5644:17, 5645:7
otherwise [6] -
5445:13, 5492:21,
5602:12, 5635:10,
5718:2, 5722:12
Ottawa [1] - 5673:4
ourselves [1] - 5395:5

outcome [2] - 5450:3,
5450:4
outcomes [1] -
5718:17
outlay [1] - 5426:3
outliers [2] - 5432:14,
5615:11
Outlook [4] - 5664:10,
5664:16, 5664:20
outset [1] - 5386:18
outside [3] - 5386:23,
5392:16, 5418:17
outstanding [2] -
5396:9, 5721:3
overall [1] - 5657:14
overlap [7] - 5488:2,
5488:11, 5489:5,
5490:9, 5490:24,
5491:1, 5491:10
overrule [1] - 5585:20
overruling [1] -
5651:11
overseeing [1] -
5588:3
overseen [1] -
5657:21
overview [1] - 5704:23
owed [2] - 5561:15,
5561:20
own [23] - 5384:23,
5385:13, 5463:10,
5466:21, 5469:12,
5469:13, 5471:6,
5472:1, 5477:20,
5547:6, 5562:3,
5570:6, 5570:20,
5571:5, 5578:25,
5587:14, 5589:10,
5591:12, 5612:3,
5676:1, 5681:7,
5684:14, 5685:22

P

p.m [9] - 5381:6,
5559:4, 5583:25,
5586:14, 5616:23,
5619:5, 5649:22,
5651:13, 5722:18
Pacific [1] - 5636:18
package [5] - 5525:5,
5525:25, 5558:6,
5679:10, 5679:21
packages [1] -
5558:21
PAGE [1] - 5379:2
page [29] - 5391:23,
5430:16, 5437:11,
5455:7, 5461:16,
5517:16, 5528:11,

5548:7, 5549:9,
5611:19, 5628:13,
5628:16, 5678:13,
5678:15, 5685:7,
5692:4, 5692:7,
5696:5, 5696:6,
5696:8, 5699:10,
5710:20, 5710:21,
5712:25, 5713:1,
5713:2, 5717:18,
5717:19, 5718:13
Page [1] - 5379:11
pages [1] - 5438:4
paid [47] - 5408:24,
5409:21, 5410:3,
5411:13, 5411:24,
5412:6, 5420:16,
5423:18, 5424:13,
5426:10, 5436:18,
5438:17, 5469:22,
5469:25, 5479:19,
5480:21, 5515:6,
5515:15, 5515:18,
5516:6, 5546:10,
5565:25, 5572:21,
5574:22, 5575:3,
5575:19, 5583:20,
5584:3, 5584:8,
5592:11, 5595:4,
5595:16, 5596:3,
5597:9, 5597:25,
5611:6, 5613:12,
5613:16, 5613:18,
5613:19, 5622:23,
5632:14, 5633:5,
5690:5, 5692:10,
5693:10, 5710:3
panics [1] - 5526:22
paper [2] - 5395:19,
5395:24
papers [1] - 5552:21
paragraph [4] -
5570:5, 5622:5,
5683:15, 5718:11
paragraphs [1] -
5689:20
parameters [7] -
5418:11, 5418:12,
5513:5, 5513:7,
5561:24, 5619:19,
5629:16
paraphrases [1] -
5388:18
parse [2] - 5633:3,
5679:14
part [32] - 5383:14,
5396:8, 5420:20,
5423:5, 5423:20,
5462:23, 5483:10,
5489:4, 5515:13,

5524:15, 5529:25,
5551:22, 5569:16,
5577:14, 5606:5,
5613:13, 5613:17,
5613:21, 5621:7,
5622:1, 5633:7,
5640:6, 5640:9,
5649:23, 5649:24,
5650:3, 5680:10,
5690:7, 5700:12,
5703:15, 5715:2
Part [2] - 5513:24,
5577:3
participant [2] -
5473:20, 5474:8
participant's [1] -
5474:11
participants [1] -
5473:21
participate [2] -
5690:4, 5691:3
participating [2] -
5688:16, 5707:11
participation [2] -
5690:6, 5703:24
particular [2] -
5534:19, 5581:10
particularly [1] -
5551:2
parties [3] - 5384:8,
5391:2, 5396:11
Partners [6] - 5469:18,
5470:5, 5472:5,
5475:2, 5476:7,
5477:12
partners [2] - 5594:16,
5704:22
party [5] - 5468:25,
5470:11, 5475:10,
5611:16, 5666:18
past [4] - 5413:13,
5427:15, 5490:1,
5578:4
patient [28] - 5418:8,
5418:25, 5419:6,
5429:7, 5444:19,
5460:24, 5486:17,
5488:9, 5502:6,
5510:17, 5516:12,
5569:21, 5570:2,
5570:15, 5570:19,
5571:3, 5571:25,
5572:5, 5576:23,
5580:10, 5581:3,
5620:7, 5620:20,
5620:22, 5621:21,
5628:17, 5628:25,
5629:9
patient's [2] -
5512:18, 5594:22

United States District Court
District of New Jersey

patient-related [1] - 5429:7

patients [39] - 5415:9, 5417:21, 5418:17, 5419:15, 5426:20, 5427:15, 5443:17, 5443:25, 5444:22, 5445:11, 5446:6, 5446:12, 5450:10, 5461:3, 5481:11, 5481:12, 5481:17, 5486:22, 5486:23, 5487:3, 5487:4, 5508:9, 5512:15, 5516:19, 5527:13, 5535:6, 5535:19, 5538:9, 5551:7, 5551:17, 5574:19, 5577:4, 5599:6, 5615:22, 5622:13, 5623:10, 5623:12, 5674:19, 5693:18

patterns [2] - 5446:24, 5447:10

Paul [1] - 5378:17

pause [1] - 5559:6

paused [1] - 5715:6

pay [10] - 5501:2, 5501:16, 5516:3, 5560:23, 5577:4, 5577:17, 5585:16, 5594:7, 5611:1, 5632:15

paying [8] - 5412:3, 5425:11, 5426:3, 5582:18, 5582:20, 5586:20, 5595:17, 5700:1

payment [6] - 5478:21, 5595:22, 5596:8, 5599:2, 5612:22, 5622:15

payments [4] - 5409:14, 5424:12, 5613:10

payor [1] - 5615:6

payors [22] - 5399:19, 5411:8, 5411:21, 5412:6, 5414:2, 5424:7, 5425:14, 5479:8, 5480:14, 5480:21, 5482:11, 5483:2, 5484:9, 5485:4, 5485:17, 5486:3, 5491:9, 5492:9, 5493:23, 5579:17, 5603:12, 5613:24

pays [1] - 5579:4

pen [2] - 5395:19,

5395:24

Penelow [78] - 5533:7, 5533:13, 5533:21, 5534:1, 5534:19, 5608:16, 5609:3, 5637:22, 5637:24, 5638:2, 5638:4, 5639:3, 5639:9, 5639:18, 5639:23, 5640:2, 5640:16, 5641:5, 5641:13, 5641:15, 5641:24, 5642:4, 5642:7, 5642:11, 5643:1, 5643:4, 5643:7, 5643:20, 5644:1, 5644:6, 5644:9, 5644:24, 5645:5, 5645:11, 5645:15, 5645:18, 5645:21, 5646:9, 5646:25, 5647:15, 5647:19, 5647:21, 5648:4, 5648:11, 5648:18, 5649:16, 5650:1, 5651:2, 5651:19, 5651:22, 5652:16, 5653:5, 5654:14, 5655:15, 5655:18, 5656:1, 5656:17, 5656:25, 5657:2, 5658:16, 5658:25, 5659:4, 5661:22, 5662:13, 5662:23, 5663:4, 5663:9, 5665:11, 5665:22, 5666:1, 5666:14, 5667:11, 5668:13, 5668:19, 5669:6, 5669:19, 5669:25, 5670:5

Penelow's [3] - 5638:23, 5644:16, 5652:8

people [69] - 5409:5, 5414:21, 5416:10, 5431:4, 5432:14, 5434:25, 5435:1, 5435:3, 5441:3, 5441:15, 5444:21, 5445:3, 5445:6, 5446:3, 5448:20, 5449:17, 5450:10, 5456:10, 5456:12, 5477:18, 5507:23, 5510:16, 5512:22, 5516:15, 5524:3, 5525:17, 5526:22, 5534:9, 5534:13, 5541:8, 5563:15, 5568:19, 5568:20,

5570:6, 5582:10, 5582:12, 5589:13, 5589:25, 5595:5, 5601:19, 5602:1, 5606:22, 5608:24, 5609:1, 5609:23, 5615:17, 5615:18, 5615:22, 5620:25, 5623:6, 5623:12, 5630:6, 5630:12, 5630:17, 5633:7, 5657:20, 5674:6, 5674:24, 5676:22, 5676:25, 5679:13, 5691:16, 5693:25, 5707:4, 5707:23, 5708:5, 5708:23, 5709:9, 5710:7

people's [1] - 5707:5

per [16] - 5425:22, 5425:24, 5437:23, 5437:24, 5438:1, 5439:14, 5473:20, 5474:4, 5474:8, 5474:11, 5476:18, 5478:1, 5588:22, 5602:22, 5625:3

perceive [1] - 5647:21

percent [83] - 5414:19, 5428:10, 5428:11, 5429:1, 5429:3, 5429:4, 5429:5, 5429:9, 5429:17, 5429:23, 5432:20, 5434:10, 5434:13, 5434:16, 5435:9, 5448:9, 5450:7, 5451:25, 5452:3, 5456:2, 5457:22, 5458:25, 5459:21, 5460:3, 5460:17, 5461:3, 5461:14, 5461:16, 5461:22, 5461:25, 5462:6, 5462:15, 5462:18, 5465:23, 5466:7, 5466:10, 5466:14, 5491:23, 5508:1, 5508:4, 5522:5, 5527:18, 5531:22, 5531:23, 5534:13, 5545:11, 5545:13, 5545:14, 5545:24, 5546:5, 5553:4, 5553:6, 5553:7, 5560:18, 5568:2, 5584:13, 5584:25, 5585:15, 5585:19, 5585:23, 5585:25, 5587:4, 5598:19, 5599:4, 5599:5,

5599:8, 5600:18, 5601:22, 5601:23, 5606:22, 5607:17, 5608:25, 5609:13, 5609:15, 5614:25, 5623:19, 5624:22, 5624:23, 5625:9, 5625:10, 5625:11, 5625:13, 5666:13

percentage [15] - 5414:17, 5433:21, 5433:22, 5434:1, 5451:23, 5456:1, 5459:25, 5460:17, 5462:16, 5462:17, 5466:5, 5586:25, 5598:21, 5598:25, 5599:3

Peredo [2] - 5614:12, 5615:2

perfect [5] - 5393:1, 5441:12, 5624:22, 5625:20, 5706:6

perfectly [2] - 5439:16, 5489:17

perform [14] - 5403:15, 5414:13, 5421:11, 5430:13, 5434:19, 5434:20, 5440:10, 5440:18, 5451:4, 5458:1, 5458:4, 5601:24, 5631:6, 5633:4

performance [1] - 5637:17

Performance [1] - 5710:23

performed [10] - 5442:23, 5465:7, 5471:14, 5475:3, 5478:19, 5554:4, 5591:10, 5632:2, 5632:23, 5694:9

performing [2] - 5597:4, 5714:14

perhaps [2] - 5464:19, 5663:21

period [42] - 5392:18, 5413:25, 5414:6, 5415:17, 5416:25, 5417:8, 5419:7, 5425:21, 5428:13, 5443:18, 5444:1, 5445:3, 5451:16, 5455:18, 5455:22, 5459:3, 5459:22, 5471:17, 5473:6, 5474:14, 5475:5, 5480:5, 5481:16, 5517:12, 5517:18,

5521:13, 5531:4, 5535:16, 5543:16, 5590:23, 5591:6, 5591:10, 5621:2, 5629:14, 5629:16, 5637:8, 5648:19, 5651:5, 5651:21, 5658:1, 5669:16

periods [2] - 5470:20, 5670:2

perish [1] - 5408:7

permission [4] - 5494:10, 5517:4, 5521:17, 5639:13

permit [1] - 5518:13

permitted [3] - 5685:21, 5686:5, 5689:25

person [33] - 5420:18, 5420:20, 5431:19, 5431:20, 5432:16, 5437:20, 5444:17, 5445:25, 5447:24, 5467:8, 5479:23, 5488:9, 5510:11, 5517:20, 5534:7, 5544:12, 5563:20, 5568:18, 5568:20, 5568:23, 5572:22, 5574:23, 5588:2, 5626:5, 5638:5, 5656:10, 5661:22, 5689:7, 5691:2, 5691:16, 5693:16, 5695:2, 5702:15

personally [2] - 5595:21, 5609:7

pertain [1] - 5381:8

Pete [1] - 5380:10

PETE [1] - 5378:14

Peterson [1] - 5660:4

Ph.D [2] - 5400:2, 5438:19

pharma [1] - 5602:20

pharmaceutical [13] - 5401:16, 5407:4, 5477:7, 5478:6, 5545:6, 5582:15, 5582:18, 5586:20, 5595:15, 5595:16, 5596:8, 5656:23, 5671:16

Pharmaceuticals [1] - 5672:17

pharmacies [6] - 5407:6, 5407:7, 5419:23, 5420:7, 5625:23, 5626:3

pharmacist [1] - 5608:8

pharmacists [1] -
5699:6
phone [13] - 5454:16,
5638:23, 5648:23,
5652:15, 5655:18,
5655:20, 5661:24,
5662:10, 5662:12,
5662:23, 5663:4,
5664:11, 5664:21
photos [2] - 5593:22,
5593:23
phrasing [1] - 5422:2
physical [1] - 5669:15
physically [3] -
5669:18, 5669:21,
5669:22
physician [37] -
5416:1, 5447:25,
5448:23, 5457:23,
5461:12, 5461:15,
5462:9, 5465:22,
5469:5, 5469:6,
5485:18, 5485:21,
5500:4, 5500:20,
5501:17, 5501:24,
5537:2, 5540:12,
5540:23, 5540:25,
5541:4, 5542:7,
5550:1, 5560:5,
5563:4, 5571:16,
5572:17, 5579:23,
5581:6, 5599:6,
5605:21, 5614:22,
5619:14, 5689:23
physician's [2] -
5468:22, 5550:20
physicians [73] -
5417:10, 5422:24,
5423:10, 5428:22,
5433:18, 5443:12,
5443:20, 5444:2,
5446:16, 5447:3,
5447:5, 5449:6,
5454:24, 5457:3,
5459:6, 5460:17,
5461:2, 5461:20,
5461:22, 5462:12,
5465:23, 5466:5,
5466:15, 5468:12,
5470:20, 5470:21,
5471:8, 5479:13,
5479:14, 5482:16,
5482:25, 5483:3,
5484:24, 5485:9,
5505:18, 5507:15,
5507:21, 5508:8,
5509:3, 5536:8,
5540:5, 5540:18,
5540:21, 5549:11,
5550:6, 5550:7,

5551:24, 5552:7,
5552:8, 5554:18,
5554:20, 5555:4,
5555:9, 5567:24,
5568:2, 5568:14,
5580:16, 5581:10,
5581:11, 5597:8,
5598:8, 5598:15,
5598:16, 5600:23,
5601:1, 5606:17,
5616:2, 5630:23,
5642:5, 5676:25,
5718:25
physicians' [3] -
5411:19, 5464:20,
5465:15
pick [5] - 5387:24,
5531:24, 5597:3,
5597:16
picking [3] - 5532:1,
5532:4, 5601:25
picture [1] - 5522:3
pieces [2] - 5549:10,
5647:7
pill [1] - 5674:20
PILM [13] - 5469:16,
5469:18, 5470:18,
5471:25, 5472:5,
5472:24, 5474:14,
5475:7, 5476:12,
5477:6, 5532:15,
5602:18
PILM's [2] - 5471:6,
5477:20
Pittsburgh [1] -
5652:3
place [8] - 5517:19,
5563:4, 5564:7,
5565:6, 5622:24,
5643:24, 5646:18,
5669:19
placed [2] - 5383:17,
5608:12
places [2] - 5473:16,
5595:12
plain [5] - 5445:24,
5446:1, 5446:10,
5503:6, 5503:7
Plaintiffs [1] - 5378:4
plan [1] - 5389:4
Plan [5] - 5513:17,
5514:2, 5514:11,
5514:18, 5518:14
planning [2] -
5637:18, 5641:21
planning-type [1] -
5641:21
plant [2] - 5607:8,
5608:12
play [6] - 5526:5,

5621:3, 5638:11,
5638:15, 5639:19,
5668:16
played [7] - 5524:15,
5638:18, 5639:21,
5653:19, 5661:16,
5667:15, 5668:17
plays [1] - 5396:3
plenty [1] - 5420:5
plot [2] - 5455:3,
5455:4
plug [1] - 5393:19
plus [5] - 5599:23,
5600:2, 5600:5,
5601:14, 5626:11
pocket [3] - 5515:20,
5589:17, 5613:15
pockets [1] - 5407:21
POI [1] - 5459:9
point [38] - 5383:12,
5384:7, 5384:13,
5384:18, 5386:22,
5389:21, 5391:16,
5391:18, 5391:21,
5392:11, 5392:15,
5394:3, 5394:14,
5395:17, 5420:1,
5438:16, 5463:14,
5489:15, 5553:8,
5564:23, 5578:21,
5615:10, 5625:18,
5630:10, 5641:23,
5642:3, 5642:9,
5643:16, 5643:23,
5644:11, 5644:22,
5669:3, 5669:6,
5674:10, 5708:10,
5716:18, 5719:4,
5720:5
pointed [5] - 5489:16,
5554:16, 5554:24,
5555:3, 5591:16
points [1] - 5410:22
policies [3] - 5678:8,
5690:25, 5704:20
policy [24] - 5677:11,
5677:21, 5678:2,
5678:8, 5681:9,
5683:25, 5685:5,
5687:8, 5692:5,
5692:9, 5692:15,
5694:3, 5696:5,
5696:12, 5699:12,
5700:5, 5700:19,
5703:10, 5704:3,
5706:11, 5715:9,
5717:14, 5717:15
population [1] -
5486:18
portion [2] - 5387:18,

5588:19
posed [2] - 5537:20,
5655:24
position [12] -
5385:10, 5420:2,
5464:21, 5626:1,
5641:13, 5651:22,
5656:23, 5657:21,
5658:4, 5672:10,
5672:16, 5673:22
positions [1] - 5658:5
positive [1] - 5443:5
positively [1] - 5443:6
possibility [3] -
5393:4, 5452:15,
5490:14
possible [9] - 5488:7,
5490:10, 5570:13,
5574:19, 5595:5,
5626:1, 5647:2,
5669:21, 5669:22
possibly [1] - 5649:2
post [8] - 5470:20,
5470:21, 5470:23,
5585:4, 5585:6,
5585:11, 5586:1,
5713:24
post-program [3] -
5470:20, 5470:21,
5470:23
post-verdict [3] -
5585:4, 5585:6,
5585:11
potential [9] - 5385:1,
5434:20, 5489:5,
5489:7, 5490:9,
5491:1, 5558:21,
5624:16, 5718:17
potentially [1] -
5674:1
PowerPoint [4] -
5514:2, 5515:25,
5518:1, 5712:13
Practical [1] - 5405:18
practically [1] -
5679:8
practice [11] -
5437:21, 5556:4,
5606:4, 5679:6,
5693:1, 5693:3,
5693:13, 5693:17,
5697:12, 5700:18,
5701:2
practices [1] -
5599:16
practicing [1] -
5574:17
practitioners [1] -
5699:5
pre [3] - 5470:20,

5585:7, 5717:7
pre-approved [1] -
5717:7
pre-verdict [1] -
5585:7
predetermined [1] -
5700:11
prefer [1] - 5596:11
preference [1] -
5390:13
prejudicial [1] -
5617:10
prep [1] - 5608:7
preparation [1] -
5441:13
prepare [2] - 5594:17,
5616:11
prepared [8] -
5381:22, 5384:9,
5441:5, 5642:17,
5720:17, 5720:19,
5721:1
preparing [2] -
5441:11, 5441:18
prescribe [43] -
5408:24, 5430:14,
5430:18, 5433:8,
5434:11, 5434:13,
5434:15, 5436:7,
5437:17, 5437:18,
5438:1, 5438:2,
5438:20, 5438:21,
5439:13, 5439:18,
5447:3, 5451:1,
5451:15, 5452:22,
5457:4, 5457:15,
5460:4, 5460:7,
5461:23, 5468:18,
5509:3, 5547:8,
5550:15, 5550:20,
5551:13, 5551:14,
5568:17, 5568:21,
5570:21, 5571:5,
5576:22, 5577:1,
5577:2, 5599:7,
5614:6, 5614:10,
5633:1
prescribed [52] -
5409:11, 5417:23,
5428:10, 5428:12,
5429:8, 5429:17,
5430:1, 5430:9,
5433:1, 5433:19,
5433:21, 5434:1,
5434:6, 5434:16,
5436:24, 5437:6,
5437:9, 5440:20,
5441:22, 5444:16,
5447:15, 5449:22,
5451:6, 5451:7,

United States District Court
District of New Jersey

5451:8, 5454:25,
5459:7, 5459:17,
5460:18, 5486:17,
5486:22, 5488:7,
5503:2, 5503:25,
5509:12, 5509:17,
5516:12, 5549:20,
5549:24, 5577:9,
5581:6, 5612:9,
5615:25, 5620:7,
5622:15, 5622:24,
5623:3, 5632:15,
5632:17, 5632:21,
5633:5, 5633:12

prescriber [13] -
5416:2, 5416:5,
5417:5, 5423:3,
5431:12, 5432:15,
5502:7, 5505:5,
5505:6, 5508:1,
5509:11, 5553:3,
5569:13

prescribers [18] -
5399:15, 5410:15,
5452:19, 5470:22,
5476:14, 5476:21,
5505:17, 5507:20,
5548:3, 5553:3,
5553:4, 5553:19,
5553:23, 5554:2,
5554:8, 5568:6

prescribers' [1] -
5632:18

prescribes [3] -
5448:11, 5527:12,
5623:18

prescribing [59] -
5410:8, 5410:16,
5424:12, 5436:5,
5436:14, 5436:19,
5437:16, 5438:9,
5438:25, 5443:11,
5446:24, 5447:10,
5448:24, 5449:6,
5451:22, 5456:5,
5456:14, 5456:20,
5456:24, 5456:25,
5458:6, 5458:22,
5459:21, 5461:9,
5462:12, 5464:20,
5465:15, 5468:22,
5469:13, 5470:19,
5475:8, 5475:12,
5475:17, 5478:4,
5502:19, 5504:22,
5509:7, 5509:22,
5510:4, 5546:11,
5551:3, 5552:7,
5552:10, 5553:18,
5555:5, 5557:20,

5568:14, 5568:20,
5594:21, 5597:12,
5597:13, 5599:19,
5615:24, 5623:4,
5623:14, 5632:11,
5632:18, 5633:4

prescription [90] -
5410:15, 5411:1,
5411:19, 5418:16,
5420:20, 5422:25,
5423:19, 5425:25,
5426:20, 5428:17,
5432:13, 5437:20,
5437:24, 5438:6,
5438:23, 5442:4,
5442:15, 5443:1,
5452:4, 5453:5,
5456:16, 5457:23,
5458:10, 5458:19,
5460:19, 5465:3,
5469:2, 5471:4,
5473:19, 5474:3,
5474:4, 5474:5,
5474:6, 5476:4,
5477:25, 5479:15,
5487:5, 5490:12,
5498:19, 5499:9,
5499:16, 5502:6,
5502:12, 5502:14,
5502:19, 5505:5,
5511:13, 5511:15,
5544:16, 5544:22,
5546:4, 5560:6,
5560:10, 5560:22,
5561:5, 5569:17,
5571:15, 5571:20,
5572:22, 5572:25,
5573:14, 5575:22,
5577:13, 5577:17,
5611:25, 5612:14,
5614:15, 5619:14,
5620:7, 5620:19,
5623:11, 5625:3,
5625:5, 5625:6,
5626:2, 5627:18,
5627:23, 5629:9,
5632:25, 5633:1,
5698:4, 5698:6,
5703:3, 5703:4,
5711:5, 5712:4,
5713:23, 5713:24

prescriptions [113] -
5409:17, 5410:4,
5411:20, 5412:3,
5414:1, 5414:5,
5417:21, 5419:14,
5419:20, 5420:15,
5423:8, 5423:25,
5425:12, 5426:7,
5426:14, 5427:15,
5428:6, 5428:11,

5429:23, 5432:20,
5438:18, 5440:6,
5444:2, 5448:9,
5448:25, 5451:24,
5456:17, 5459:25,
5460:1, 5462:1,
5471:8, 5472:1,
5473:20, 5474:9,
5477:1, 5477:15,
5478:1, 5479:7,
5479:20, 5480:2,
5480:17, 5482:7,
5482:11, 5482:15,
5482:25, 5483:2,
5483:14, 5483:20,
5484:1, 5484:2,
5484:7, 5484:9,
5484:18, 5484:24,
5485:5, 5497:16,
5498:1, 5498:12,
5498:18, 5499:4,
5499:14, 5501:2,
5501:16, 5502:7,
5503:12, 5505:4,
5505:13, 5505:25,
5506:1, 5506:3,
5507:17, 5507:25,
5508:8, 5515:15,
5545:5, 5546:14,
5550:7, 5551:24,
5551:25, 5557:3,
5562:7, 5564:9,
5564:10, 5564:15,
5565:20, 5565:25,
5566:22, 5569:2,
5569:13, 5569:23,
5572:7, 5572:10,
5572:16, 5572:20,
5573:2, 5573:4,
5573:19, 5575:10,
5580:15, 5581:11,
5596:18, 5602:4,
5619:15, 5692:13,
5697:23, 5698:23,
5710:25, 5711:18,
5711:23, 5711:24,
5713:12, 5714:2,
5714:6

presence [1] -
5606:17

present [14] - 5399:17,
5413:16, 5413:17,
5492:21, 5557:23,
5610:21, 5619:25,
5685:19, 5689:24,
5690:1, 5691:7,
5704:20, 5706:17

presentation [12] -
5468:25, 5514:2,
5544:10, 5546:9,
5579:17, 5596:25,

5634:11, 5634:22,
5686:5, 5697:13,
5704:24, 5712:13

presentations [3] -
5543:9, 5544:7,
5605:17

presented [9] -
5464:23, 5575:21,
5609:19, 5616:7,
5628:24, 5645:6,
5645:9, 5678:23,
5679:6

presenting [2] -
5396:22, 5681:1

preserve [1] - 5389:11

preserving [1] -
5390:13

president [2] -
5610:13, 5673:11

pressure [1] - 5609:5

pressured [1] -
5641:25

presume [1] - 5390:1

pretrial [1] - 5393:21

pretty [3] - 5489:7,
5654:14, 5654:25

prevent [2] - 5395:9,
5395:20

preventing [1] -
5525:7

previous [1] - 5434:3

previously [5] -
5389:8, 5393:4,
5419:15, 5654:10,
5659:9

Prezista [174] -
5410:4, 5412:6,
5412:23, 5412:25,
5413:25, 5414:1,
5414:5, 5414:8,
5414:9, 5414:11,
5414:13, 5414:15,
5414:17, 5414:18,
5414:24, 5417:20,
5417:23, 5418:5,
5418:16, 5418:18,
5419:5, 5419:17,
5420:15, 5422:25,
5423:8, 5423:19,
5425:13, 5425:16,
5426:8, 5426:14,
5428:6, 5428:10,
5428:20, 5429:22,
5429:23, 5430:10,
5430:14, 5430:18,
5432:20, 5432:25,
5433:2, 5433:8,
5433:21, 5434:2,
5434:6, 5434:11,
5434:17, 5436:7,

5436:24, 5437:6,
5438:25, 5440:5,
5443:18, 5443:25,
5447:4, 5447:8,
5447:18, 5447:19,
5447:20, 5448:12,
5449:6, 5451:1,
5451:15, 5451:24,
5452:22, 5453:23,
5454:25, 5456:21,
5457:4, 5457:15,
5459:10, 5459:13,
5459:17, 5459:21,
5460:8, 5460:18,
5461:3, 5461:16,
5461:17, 5461:18,
5461:25, 5462:1,
5462:7, 5477:16,
5477:25, 5478:11,
5478:16, 5478:22,
5479:7, 5479:15,
5479:20, 5480:3,
5481:5, 5482:7,
5482:10, 5482:14,
5482:24, 5483:19,
5483:20, 5483:25,
5484:2, 5484:7,
5484:9, 5485:6,
5486:4, 5486:5,
5486:6, 5486:10,
5486:16, 5486:22,
5486:24, 5487:5,
5487:18, 5487:19,
5487:24, 5487:25,
5488:7, 5490:12,
5497:16, 5498:12,
5498:17, 5502:13,
5503:16, 5503:17,
5503:25, 5509:22,
5510:4, 5510:10,
5511:12, 5518:6,
5520:17, 5521:8,
5522:6, 5527:20,
5528:21, 5531:1,
5532:12, 5532:16,
5536:3, 5537:2,
5538:1, 5538:9,
5549:20, 5549:25,
5564:15, 5573:14,
5576:2, 5576:5,
5576:11, 5576:15,
5576:22, 5577:9,
5581:6, 5607:15,
5619:15, 5619:21,
5620:8, 5621:14,
5628:16, 5629:9,
5630:9, 5632:21,
5633:6, 5633:12,
5676:10, 5676:12,
5676:13, 5677:22,
5678:4, 5678:9,

5532:19, 5534:4,
5574:18, 5674:5,
5676:21, 5677:2,
5699:4, 5699:5,
5701:17, 5701:22,
5707:23
provides [3] -
5420:23, 5421:12,
5696:12
providing [4] -
5399:13, 5420:12,
5422:22, 5479:1
provision [3] -
5683:25, 5717:22,
5718:14
Provision [2] -
5716:19, 5716:25
provisions [5] -
5678:17, 5715:9,
5716:17, 5717:14,
5718:9
proviso [1] - 5389:6
public [1] - 5578:8
publish [3] - 5404:17,
5408:7, 5677:18
published [2] -
5543:21, 5693:3
pull [8] - 5506:7,
5534:3, 5534:22,
5576:6, 5596:24,
5611:22, 5687:12,
5705:8
pulled [2] - 5614:5,
5614:13
pump [1] - 5672:6
purchase [1] - 5718:3
purchasing [1] -
5697:23
pure [1] - 5408:5
purport [1] - 5579:21
purpose [8] - 5399:16,
5436:11, 5471:23,
5596:9, 5698:7,
5699:1, 5699:7,
5714:17
purposes [17] -
5391:10, 5415:25,
5416:6, 5422:6,
5427:23, 5483:6,
5500:2, 5501:14,
5502:4, 5514:17,
5531:15, 5546:25,
5571:21, 5572:15,
5637:8, 5698:22,
5720:25
purse [1] - 5638:24
pursuant [1] - 5515:10
pursuing [6] -
5400:25, 5401:3,
5401:6, 5401:17,

5401:23, 5402:3
pushed [2] - 5575:2,
5606:8
pushing [1] - 5512:24
put [40] - 5380:24,
5384:22, 5389:8,
5393:18, 5395:19,
5395:24, 5402:19,
5436:11, 5452:23,
5470:25, 5494:22,
5494:25, 5495:3,
5504:7, 5504:15,
5506:6, 5507:6,
5521:19, 5522:3,
5541:14, 5560:10,
5560:22, 5579:16,
5582:23, 5585:5,
5585:8, 5585:11,
5585:17, 5589:9,
5593:19, 5594:12,
5609:21, 5630:9,
5634:14, 5673:10,
5694:16, 5695:14,
5701:25, 5705:24,
5720:20
putting [3] - 5534:16,
5589:16, 5640:22

Q

QD [1] - 5626:17
qualification [2] -
5510:23, 5697:9
qualifications [1] -
5696:14
qualified [1] - 5640:25
quality [1] - 5517:23
quantitative [2] -
5400:10, 5402:9
quantity [1] - 5696:14
quarter [7] - 5457:9,
5457:10, 5474:22,
5474:23, 5581:1,
5627:6
quartile [7] - 5457:10,
5457:11, 5457:13,
5457:19, 5457:22,
5457:23
quartiles [2] - 5457:5,
5457:8
QUESTION [3] -
5607:7, 5609:13,
5610:16
questioned [1] -
5575:8
questioning [4] -
5586:10, 5631:2,
5646:12, 5648:22
questions [28] -
5382:13, 5399:8,

5421:23, 5494:6,
5537:19, 5546:23,
5574:2, 5593:8,
5597:19, 5608:9,
5608:14, 5610:4,
5610:8, 5610:25,
5621:12, 5623:21,
5623:24, 5630:21,
5646:10, 5647:8,
5648:21, 5652:22,
5668:7, 5670:8,
5671:8, 5683:2,
5683:16, 5683:18
quick [2] - 5381:1,
5404:24
quickly [7] - 5393:18,
5406:6, 5417:19,
5715:15, 5716:18,
5721:17, 5722:9
quite [11] - 5404:15,
5408:11, 5411:15,
5513:14, 5604:2,
5614:2, 5630:8,
5648:18, 5676:16,
5709:14
quits [1] - 5526:2
quote [9] - 5500:20,
5504:1, 5504:9,
5504:23, 5505:14,
5513:6, 5565:19,
5572:17, 5583:17
QURAISHI [2] -
5378:11, 5380:2

R

race [1] - 5517:21
raise [10] - 5383:6,
5389:22, 5390:10,
5391:21, 5392:16,
5495:19, 5496:8,
5561:15, 5578:21,
5583:19
raised [9] - 5386:8,
5386:25, 5392:8,
5393:4, 5631:5,
5640:22, 5646:4,
5647:15, 5661:4
raising [2] - 5618:12,
5639:23
ran [5] - 5444:25,
5449:12, 5458:7,
5631:23
range [3] - 5474:20,
5693:9
rank [20] - 5431:19,
5431:20, 5432:4,
5432:14, 5433:5,
5433:6, 5439:7,
5440:13, 5440:14,

5441:4, 5441:9,
5441:19, 5441:21,
5442:9, 5448:6,
5457:18, 5457:19,
5458:1, 5458:2,
5467:7
ranked [1] - 5458:9
ranking [2] - 5439:10,
5440:19
ranks [1] - 5657:17
rare [3] - 5450:14,
5517:20, 5560:13
rarely [7] - 5429:12,
5570:12, 5570:13,
5570:17, 5621:10,
5621:11, 5622:6
rate [15] - 5406:9,
5552:2, 5552:4,
5552:6, 5552:10,
5553:18, 5555:16,
5557:3, 5557:20,
5587:21, 5588:13,
5588:23, 5623:4,
5623:14
rates [4] - 5410:15,
5410:16, 5411:19,
5614:14
rather [3] - 5382:16,
5384:10, 5393:16
ratio [8] - 5432:24,
5433:4, 5434:21,
5447:8, 5447:18,
5451:6, 5462:12
rationale [1] - 5694:13
RDR [1] - 5723:11
re [1] - 5651:10
reached [2] - 5477:12,
5673:6
react [1] - 5385:17
reaction [2] - 5412:25,
5639:6
reactions [3] -
5412:22, 5413:21
read [34] - 5380:24,
5380:25, 5405:17,
5430:23, 5462:4,
5464:24, 5465:9,
5477:18, 5504:10,
5504:13, 5510:7,
5510:14, 5518:9,
5524:12, 5524:14,
5524:17, 5529:10,
5529:23, 5530:14,
5534:15, 5536:1,
5536:18, 5536:23,
5536:24, 5543:25,
5544:12, 5548:20,
5552:21, 5556:23,
5563:19, 5598:6,
5606:12, 5620:16

readback [1] -
5604:18
reading [6] - 5563:13,
5588:8, 5588:22,
5604:21, 5608:23,
5609:9
ready [16] - 5387:2,
5397:1, 5397:7,
5398:8, 5398:23,
5463:22, 5464:4,
5507:11, 5559:18,
5634:10, 5635:2,
5635:17, 5674:3,
5686:21, 5687:2,
5719:14
real [15] - 5446:13,
5469:11, 5469:14,
5469:22, 5469:24,
5471:14, 5471:16,
5475:15, 5475:21,
5475:23, 5477:12,
5552:22, 5572:1,
5575:13
real-life [1] - 5552:22
real-time [2] -
5469:22, 5475:21
realized [1] - 5568:20
really [43] - 5381:23,
5408:18, 5409:2,
5409:5, 5413:1,
5417:17, 5422:2,
5425:20, 5427:5,
5432:13, 5435:18,
5435:24, 5437:8,
5437:10, 5438:4,
5442:10, 5445:9,
5460:12, 5528:14,
5531:12, 5561:19,
5561:20, 5562:2,
5569:9, 5570:1,
5578:7, 5588:2,
5613:17, 5615:23,
5615:25, 5616:12,
5623:14, 5625:20,
5626:7, 5627:21,
5674:18, 5674:23,
5675:8, 5720:21,
5722:1, 5722:4
reason [33] - 5387:25,
5388:19, 5404:12,
5418:2, 5425:18,
5426:17, 5426:24,
5428:2, 5438:8,
5438:21, 5444:15,
5444:18, 5454:14,
5466:2, 5525:6,
5525:18, 5526:22,
5561:10, 5561:23,
5562:3, 5572:24,
5583:1, 5615:14,

5403:3, 5407:10, 5407:25, 5428:19, 5456:7, 5478:14, 5508:24, 5509:4, 5509:5, 5510:6, 5510:7, 5510:22, 5527:8, 5527:11, 5527:15, 5527:23, 5530:13, 5530:14, 5533:1, 5533:16, 5535:9, 5535:10, 5535:17, 5535:18, 5536:5, 5536:6, 5536:7, 5536:10, 5536:11, 5536:16, 5536:17, 5537:5, 5538:4, 5539:1, 5539:4, 5539:10, 5539:11, 5544:6, 5547:10, 5548:9, 5550:24, 5551:1, 5551:4, 5551:5, 5565:6, 5567:11, 5567:12, 5567:15, 5570:10, 5570:16, 5570:17, 5570:18, 5570:22, 5610:10, 5621:6, 5621:9, 5623:20, 5624:3, 5627:12, 5640:2, 5640:20, 5640:21, 5641:16, 5641:17, 5641:19, 5647:12, 5656:25, 5657:2, 5657:9, 5657:11, 5657:13, 5658:15, 5660:24, 5662:18, 5667:17, 5667:19, 5669:2, 5669:9, 5680:19, 5687:9, 5688:24, 5709:23

remembered [3] - 5564:20, 5663:17, 5673:1

remembers [3] - 5567:8, 5567:13, 5655:15

remind [8] - 5385:23, 5397:17, 5434:25, 5450:4, 5510:1, 5559:16, 5602:7, 5614:12

reminded [3] - 5467:21, 5595:14, 5595:15

reminder [6] - 5446:15, 5464:6, 5558:18, 5558:23, 5687:3, 5721:9

remove [3] - 5489:22,

5661:1, 5689:18

removed [4] - 5488:22, 5681:23, 5684:23, 5684:25

renew [1] - 5701:6

rep [13] - 5537:8, 5540:25, 5546:5, 5550:12, 5560:5, 5561:5, 5567:3, 5567:13, 5570:2, 5641:21, 5671:17, 5672:6, 5690:8

repeat [2] - 5530:6, 5566:9

rephrase [5] - 5421:4, 5613:7, 5617:13, 5617:15, 5629:5

rephrasing [1] - 5618:2

replaced [1] - 5630:10

replies [1] - 5383:5

report [63] - 5382:8, 5471:2, 5471:6, 5471:20, 5471:25, 5473:16, 5475:19, 5476:13, 5494:24, 5495:6, 5495:12, 5495:23, 5496:1, 5496:2, 5501:19, 5501:21, 5501:23, 5504:19, 5504:20, 5504:21, 5505:12, 5505:23, 5505:24, 5506:7, 5506:12, 5506:19, 5507:14, 5512:21, 5518:18, 5534:10, 5540:6, 5547:16, 5547:17, 5548:1, 5548:3, 5548:11, 5548:23, 5549:6, 5549:7, 5552:17, 5552:25, 5554:7, 5554:17, 5556:8, 5556:23, 5562:8, 5570:5, 5570:7, 5571:25, 5572:1, 5575:14, 5580:11, 5580:18, 5622:6, 5631:12, 5641:24, 5642:4, 5644:2, 5644:19, 5645:11, 5651:22, 5665:22, 5681:16

reported [26] - 5540:12, 5642:11, 5642:14, 5642:15, 5643:12, 5643:22, 5644:8, 5644:21, 5644:22, 5644:23, 5645:22, 5646:1,

5648:11, 5648:20, 5649:17, 5651:3, 5657:23, 5657:25, 5659:9, 5659:19, 5664:2, 5665:12, 5666:4, 5669:7, 5670:5, 5684:18

Reporter [2] - 5378:23, 5723:12

REPORTER'S [1] - 5723:1

reporting [1] - 5652:18

reports [6] - 5470:18, 5471:18, 5476:1, 5514:25, 5555:18, 5651:20

represent [6] - 5653:5, 5653:13, 5682:6, 5695:22, 5701:18, 5702:23

representation [4] - 5496:17, 5601:18, 5609:18, 5702:21

representations [1] - 5718:14

representative [20] - 5416:20, 5420:3, 5454:4, 5467:11, 5468:8, 5500:9, 5535:21, 5540:7, 5540:13, 5547:2, 5562:6, 5564:5, 5564:21, 5565:15, 5565:24, 5568:13, 5569:1, 5604:9, 5604:10, 5626:3

representatives [7] - 5417:4, 5417:10, 5476:13, 5476:20, 5522:25, 5547:7, 5567:19

represented [2] - 5653:11, 5679:20

representing [2] - 5485:14, 5515:7

represents [2] - 5495:5, 5717:24

reps [10] - 5523:20, 5538:7, 5545:23, 5563:4, 5606:8, 5682:7, 5701:15, 5701:17, 5701:20, 5711:25

reputable [1] - 5701:22

reputation [1] - 5578:7

request [3] - 5690:9, 5700:11, 5720:8

requested [3] - 5518:24, 5563:15, 5721:6

requests [1] - 5666:17

required [2] - 5707:15, 5715:9

requirement [2] - 5665:21, 5699:21

Requirements [1] - 5718:12

requirements [1] - 5582:5

requires [1] - 5582:14

requiring [1] - 5699:21

research [5] - 5575:4, 5674:4, 5674:7, 5693:15, 5697:12

researcher [2] - 5693:2, 5702:18

reserve [7] - 5387:13, 5387:14, 5388:19, 5391:1, 5633:24, 5634:16

reserving [1] - 5391:8

resistance [1] - 5620:21

resolve [3] - 5392:12, 5392:15, 5396:6

resolved [1] - 5396:10

resolving [1] - 5391:19

resource [2] - 5657:21, 5662:21

resources [4] - 5644:18, 5645:8, 5709:11, 5714:23

respect [30] - 5386:4, 5387:19, 5387:20, 5395:6, 5405:23, 5406:19, 5407:6, 5412:5, 5412:21, 5413:20, 5414:10, 5415:7, 5415:11, 5418:15, 5419:18, 5422:17, 5423:6, 5426:7, 5429:21, 5456:19, 5480:20, 5481:3, 5488:25, 5492:23, 5493:14, 5493:22, 5596:12, 5606:14, 5626:20, 5690:19

respectfully [1] - 5511:1

respond [13] - 5384:22, 5385:20, 5386:12, 5393:22, 5394:9, 5394:15, 5395:4, 5395:16,

5395:17, 5395:18, 5642:18, 5688:23

responded [2] - 5642:22, 5651:19

responding [3] - 5384:24, 5386:12, 5394:22

response [23] - 5384:23, 5391:4, 5463:4, 5463:7, 5465:19, 5465:20, 5468:15, 5468:20, 5469:4, 5555:18, 5556:21, 5617:6, 5619:1, 5619:8, 5619:11, 5619:23, 5650:4, 5650:23, 5651:5, 5651:6, 5655:23, 5683:6, 5688:21

responsibilities [1] - 5673:25

responsibility [4] - 5402:21, 5636:12, 5637:14, 5657:17

responsible [6] - 5407:22, 5462:8, 5658:2, 5676:9, 5700:9, 5702:15

rest [16] - 5384:8, 5387:14, 5387:17, 5388:11, 5388:17, 5427:8, 5444:16, 5445:4, 5501:10, 5510:17, 5515:21, 5576:16, 5591:14, 5633:19, 5634:1, 5721:20

restate [1] - 5555:25

restaurant [1] - 5416:14

restaurants [1] - 5416:17

rested [2] - 5390:3, 5390:4

resting [3] - 5389:20, 5390:5, 5633:24

result [9] - 5384:20, 5399:19, 5436:13, 5442:22, 5449:25, 5453:10, 5471:4, 5546:8, 5633:9

results [7] - 5442:6, 5442:17, 5473:5, 5474:13, 5474:21, 5552:19, 5632:8

resume [1] - 5693:1

retained [4] - 5471:21, 5578:20, 5578:25, 5592:13

retrained [1] - 5681:23
retrieving [1] - 5411:5
return [17] - 5469:16, 5470:7, 5472:2, 5473:13, 5474:11, 5474:16, 5474:23, 5476:3, 5518:17, 5612:15, 5639:24, 5709:20, 5710:2, 5710:3, 5710:4, 5710:6, 5713:17
returned [1] - 5473:7
returning [1] - 5398:6
Revenue [2] - 5406:2, 5406:4
review [22] - 5381:1, 5381:20, 5381:23, 5383:1, 5383:9, 5383:20, 5517:10, 5605:24, 5606:10, 5608:2, 5679:1, 5679:7, 5679:18, 5680:15, 5681:7, 5694:18, 5695:3, 5703:1, 5717:7, 5720:21
Review [1] - 5679:13
reviewed [9] - 5383:8, 5554:6, 5554:13, 5604:21, 5606:11, 5684:4, 5699:16, 5701:4
reviewing [6] - 5383:4, 5386:17, 5606:20, 5606:21, 5607:23, 5608:5
revisited [1] - 5395:10
rewards [1] - 5479:1
Reyataz [1] - 5415:4
Ricky [6] - 5522:14, 5573:11, 5573:18, 5575:10, 5595:24, 5716:3
rides [1] - 5608:17
ridiculous [1] - 5575:6
right-hand [13] - 5426:6, 5430:25, 5438:10, 5439:15, 5441:23, 5443:24, 5444:22, 5448:2, 5448:8, 5455:5, 5456:11, 5465:24, 5482:24
rights [1] - 5389:11
rise [10] - 5380:4, 5397:23, 5464:1, 5559:3, 5559:7, 5634:23, 5635:14, 5686:18, 5686:24, 5719:20

risk [2] - 5406:24, 5418:5
Rite [1] - 5626:10
Roads [1] - 5671:14
Roche [2] - 5672:17, 5672:24
Rock [1] - 5595:4
Rodney [1] - 5378:21
ROI [9] - 5470:7, 5709:21, 5710:12, 5711:1, 5712:3, 5712:5, 5713:6, 5714:13, 5714:17
role [17] - 5636:14, 5636:16, 5636:20, 5637:9, 5654:7, 5660:19, 5669:12, 5671:18, 5671:19, 5672:11, 5672:16, 5672:18, 5673:25, 5675:11, 5675:18, 5675:21, 5703:24
roles [6] - 5636:12, 5636:16, 5637:14, 5689:2, 5689:14, 5690:18
roll [1] - 5637:15
room [1] - 5679:14
roster [2] - 5692:20, 5701:4
rotation [1] - 5637:6
rough [2] - 5627:21, 5654:25
roughly [2] - 5675:11, 5676:2
Royal [1] - 5671:14
RSVP [1] - 5689:16
rule [2] - 5621:3, 5677:12
Rule [5] - 5389:5, 5389:11, 5389:16, 5390:23, 5393:18
rules [1] - 5706:18
run [9] - 5432:9, 5432:12, 5489:16, 5678:18, 5704:24, 5708:2, 5714:7, 5714:24, 5719:9
Russ [5] - 5380:15, 5652:25, 5653:5, 5688:14, 5721:15
RUSS [17] - 5378:15, 5379:6, 5380:15, 5649:19, 5649:23, 5650:5, 5650:16, 5650:25, 5651:2, 5651:7, 5653:1, 5653:2, 5661:9, 5661:11, 5661:17, 5667:16, 5668:7

Rx [2] - 5447:20, 5713:24
RX [1] - 5425:16
RX-275 [1] - 5611:17

S

S-A-L-A-D-A-N-A [1] - 5671:4
S-H-A-K-E-D [1] - 5398:21
Sachs [1] - 5407:20
sadly [1] - 5714:4
safe [1] - 5419:4
SAFE [10] - 5695:5, 5695:8, 5695:9, 5696:15, 5696:20, 5698:10, 5699:17, 5700:13, 5702:25
safety [2] - 5678:25, 5718:16
Saint [1] - 5378:17
Saladana [23] - 5670:13, 5670:18, 5670:19, 5671:4, 5671:6, 5671:12, 5671:24, 5677:10, 5677:21, 5682:2, 5682:21, 5687:3, 5687:7, 5687:16, 5695:19, 5696:8, 5705:11, 5712:12, 5715:22, 5719:22, 5721:13, 5721:15, 5722:7
SALADANA [2] - 5379:7, 5670:25
sales [106] - 5410:7, 5414:16, 5414:23, 5415:2, 5416:20, 5417:4, 5417:9, 5444:4, 5446:17, 5453:21, 5453:22, 5454:4, 5454:11, 5454:20, 5455:17, 5467:11, 5468:8, 5469:23, 5472:1, 5473:12, 5474:15, 5476:9, 5476:13, 5476:20, 5477:6, 5484:7, 5500:9, 5508:17, 5520:17, 5521:7, 5522:5, 5522:24, 5522:25, 5523:20, 5524:9, 5527:19, 5528:20, 5530:4, 5530:11, 5530:12, 5531:17, 5532:11, 5535:21, 5537:8, 5538:7,

5539:9, 5539:14, 5540:6, 5540:13, 5540:25, 5545:23, 5546:5, 5547:2, 5547:7, 5549:15, 5550:11, 5560:5, 5561:5, 5562:6, 5563:4, 5563:10, 5564:3, 5564:4, 5564:21, 5565:14, 5565:24, 5567:3, 5567:7, 5567:8, 5567:13, 5567:19, 5568:12, 5568:13, 5568:25, 5570:2, 5602:13, 5602:16, 5604:9, 5604:10, 5606:15, 5608:17, 5636:15, 5637:7, 5637:16, 5641:21, 5657:3, 5657:12, 5666:14, 5666:16, 5671:17, 5671:18, 5682:7, 5682:11, 5687:20, 5700:8, 5700:23, 5701:3, 5701:8, 5703:6, 5703:8, 5703:15, 5703:18, 5711:25
Sales [1] - 5710:23
salespeople [2] - 5602:19, 5606:4
salesperson [1] - 5603:19
SANDERSON [1] - 5378:16
Santa [1] - 5693:19
Sara [2] - 5539:4, 5606:3
sat [3] - 5472:24, 5473:3, 5541:12
save [2] - 5452:11, 5462:14
saving [1] - 5453:1
saw [22] - 5382:11, 5383:10, 5455:10, 5468:5, 5468:6, 5474:22, 5475:25, 5478:25, 5503:24, 5534:15, 5572:21, 5602:20, 5614:11, 5631:10, 5638:20, 5638:23, 5644:16, 5644:19, 5645:4, 5645:15, 5655:24, 5665:12
scared [4] - 5667:18, 5667:22, 5668:2, 5668:4
scary [2] - 5445:25,

5490:16
schedule [1] - 5396:11
school [8] - 5402:19, 5637:2, 5652:3, 5652:6, 5654:8, 5656:20, 5671:10, 5671:13
School [2] - 5400:3, 5401:21
scope [3] - 5408:14, 5694:10, 5694:24
Score [8] - 5434:24, 5435:3, 5435:14, 5435:15, 5449:20, 5449:24, 5452:8, 5453:8
score [4] - 5510:9, 5518:19, 5521:21, 5524:7
Scott [2] - 5623:21, 5623:24
screen [9] - 5494:22, 5494:25, 5687:16, 5695:19, 5700:7, 5705:11, 5705:24, 5712:12, 5715:22
screened [1] - 5410:24
screenshot [8] - 5470:17, 5471:1, 5471:6, 5471:24, 5476:12, 5477:17, 5477:19, 5477:20
se [1] - 5588:22
seat [5] - 5380:5, 5397:24, 5559:9, 5635:16, 5687:1
seated [7] - 5397:11, 5397:16, 5463:21, 5464:3, 5559:5, 5635:1, 5686:20
second [30] - 5401:9, 5417:2, 5423:5, 5423:11, 5434:3, 5455:14, 5457:10, 5458:25, 5481:10, 5508:4, 5526:6, 5548:25, 5564:4, 5569:13, 5569:23, 5597:18, 5604:3, 5604:6, 5604:11, 5620:10, 5620:18, 5623:1, 5627:23, 5632:3, 5632:5, 5650:14, 5652:8, 5681:5, 5713:22, 5715:2
secondary [1] - 5704:17

secondly [1] - 5720:17
secret [2] - 5524:8, 5527:7
Secret [1] - 5405:1
secretly [1] - 5529:9
section [2] - 5409:20, 5704:5
Section [1] - 5570:7
security [2] - 5558:6, 5558:16
see [191] - 5381:16, 5381:18, 5383:9, 5383:13, 5383:15, 5383:19, 5385:17, 5386:11, 5393:8, 5393:10, 5393:20, 5394:4, 5394:13, 5395:2, 5395:14, 5396:2, 5396:21, 5408:19, 5408:25, 5410:17, 5412:20, 5414:15, 5414:21, 5416:24, 5419:6, 5419:14, 5421:15, 5423:11, 5425:8, 5425:19, 5428:17, 5429:10, 5430:7, 5432:19, 5432:21, 5433:8, 5433:15, 5434:4, 5434:12, 5437:1, 5437:12, 5437:17, 5439:12, 5439:21, 5440:7, 5440:18, 5440:23, 5441:23, 5442:4, 5447:23, 5450:15, 5451:17, 5455:3, 5456:3, 5456:11, 5460:16, 5461:4, 5462:5, 5463:4, 5465:25, 5466:9, 5467:2, 5469:1, 5470:24, 5471:7, 5472:3, 5472:8, 5473:9, 5473:19, 5473:23, 5474:18, 5476:10, 5477:3, 5477:8, 5478:2, 5478:8, 5482:8, 5482:17, 5484:25, 5486:8, 5489:12, 5491:24, 5506:20, 5506:22, 5507:13, 5507:20, 5511:16, 5512:3, 5512:4, 5517:2, 5528:1, 5532:24, 5537:11, 5537:12, 5541:12, 5545:18, 5548:2, 5548:14, 5549:21,

5556:14, 5563:22, 5565:16, 5565:17, 5570:7, 5570:15, 5571:18, 5571:22, 5572:8, 5574:20, 5574:25, 5575:17, 5579:19, 5579:24, 5583:24, 5596:11, 5597:12, 5597:13, 5598:10, 5598:17, 5602:2, 5602:3, 5603:6, 5604:25, 5605:14, 5614:8, 5615:2, 5621:5, 5623:7, 5627:19, 5628:18, 5628:22, 5629:8, 5629:10, 5631:10, 5632:11, 5638:25, 5643:13, 5645:7, 5646:16, 5647:3, 5648:9, 5649:3, 5663:2, 5678:17, 5678:18, 5678:20, 5679:2, 5681:5, 5682:2, 5682:21, 5682:25, 5683:3, 5683:9, 5683:22, 5685:3, 5687:16, 5687:21, 5687:25, 5688:11, 5688:18, 5689:20, 5695:19, 5696:8, 5696:17, 5697:11, 5697:15, 5697:22, 5697:25, 5699:18, 5700:7, 5700:15, 5704:10, 5705:11, 5710:24, 5712:12, 5712:15, 5713:13, 5713:22, 5714:10, 5715:14, 5715:22, 5716:2, 5716:4, 5716:22, 5717:3, 5717:9, 5718:5, 5718:21, 5721:8
seeing [1] - 5544:6
seek [1] - 5709:10
seem [2] - 5477:18, 5666:24
segment [3] - 5486:17, 5487:8, 5548:13
select [2] - 5521:24, 5703:20
selected [3] - 5696:15, 5697:19, 5698:4
selecting [3] - 5695:24, 5698:15, 5700:4
selection [6] - 5696:2,

5696:9, 5696:13, 5697:9, 5700:9
Selection [1] - 5697:22
sell [1] - 5608:18
selling [1] - 5612:16
send [4] - 5594:5, 5701:10, 5701:14, 5702:2
sending [1] - 5594:25
sense [15] - 5384:11, 5386:20, 5386:23, 5392:16, 5393:9, 5406:14, 5431:18, 5435:21, 5502:17, 5512:15, 5530:3, 5531:12, 5590:2, 5630:11, 5722:5
sensitive [1] - 5382:14
sent [4] - 5489:24, 5595:3, 5662:25, 5664:12
sentence [2] - 5530:8, 5679:18
separate [12] - 5385:13, 5400:17, 5406:3, 5412:8, 5412:9, 5415:21, 5417:15, 5420:10, 5437:13, 5439:4, 5662:21
separated [1] - 5496:4
separately [2] - 5409:16, 5491:5
separating [1] - 5393:21
September [2] - 5687:20, 5688:10
sequential [2] - 5674:24, 5674:25
serious [3] - 5412:22, 5642:19, 5706:19
seriously [2] - 5436:3, 5642:21
served [1] - 5545:6
service [1] - 5709:8
Service [6] - 5406:2, 5406:5, 5525:10, 5558:15, 5558:17, 5558:20
services [7] - 5403:15, 5403:21, 5406:15, 5408:2, 5591:10, 5692:11, 5717:25
serving [2] - 5409:22, 5579:9
set [15] - 5382:5, 5382:15, 5393:15, 5439:8, 5443:15, 5585:6, 5664:21,

5676:18, 5676:24, 5677:12, 5690:24, 5692:21, 5694:9, 5694:12, 5714:23
setoff [1] - 5585:4
setting [4] - 5641:17, 5689:8, 5695:23, 5698:21
seven [6] - 5437:21, 5448:25, 5449:3, 5465:9, 5563:19, 5701:15
several [16] - 5392:1, 5401:14, 5416:14, 5554:4, 5656:7, 5661:22, 5662:3, 5662:6, 5664:24, 5665:3, 5681:17, 5687:19, 5692:1, 5706:9, 5707:7, 5716:17
sexual [1] - 5517:21
SHAKED [1] - 5379:3
Shaked [28] - 5387:5, 5387:6, 5398:12, 5398:14, 5398:18, 5399:5, 5403:19, 5408:1, 5409:18, 5422:17, 5464:6, 5464:12, 5492:7, 5494:5, 5497:12, 5500:2, 5516:18, 5520:6, 5552:23, 5559:16, 5559:22, 5562:13, 5587:11, 5593:7, 5594:4, 5599:9, 5603:1, 5630:20
shaked [1] - 5387:7
Shaked's [1] - 5393:5
shall [3] - 5718:2, 5718:18, 5718:19
share [3] - 5414:16, 5414:20, 5415:1
shared [1] - 5499:22
shareholder [1] - 5407:8
shareholders [3] - 5407:15, 5407:20, 5407:24
shares [1] - 5414:16
sheet [1] - 5496:4
shields [1] - 5608:14
shift [1] - 5443:8
short [8] - 5397:15, 5431:13, 5463:14, 5463:20, 5634:12, 5634:25, 5686:16, 5686:19
shortcoming [1] -

5427:20
shortly [1] - 5694:3
show [32] - 5415:1, 5456:19, 5466:22, 5468:17, 5468:24, 5517:2, 5519:4, 5521:23, 5528:11, 5534:12, 5534:14, 5541:9, 5541:18, 5541:21, 5545:14, 5545:18, 5552:17, 5553:14, 5567:23, 5568:3, 5571:10, 5603:6, 5615:4, 5632:8, 5632:24, 5642:25, 5645:3, 5646:9, 5648:20, 5650:6, 5677:5, 5710:16
showed [27] - 5498:10, 5512:9, 5513:1, 5519:4, 5528:3, 5533:20, 5534:23, 5542:19, 5553:2, 5553:11, 5553:17, 5556:9, 5557:5, 5557:11, 5557:21, 5560:11, 5572:15, 5614:14, 5624:1, 5627:8, 5659:17, 5662:16, 5666:8, 5666:11
showing [4] - 5438:10, 5547:20, 5610:12, 5623:4
shown [5] - 5495:9, 5575:22, 5611:21, 5614:4, 5702:9
shows [5] - 5461:8, 5504:21, 5531:25, 5547:6, 5550:13
side [39] - 5383:4, 5416:8, 5419:4, 5420:12, 5426:2, 5426:6, 5430:20, 5430:21, 5430:25, 5431:6, 5438:10, 5439:12, 5439:15, 5441:9, 5441:23, 5441:24, 5443:24, 5444:20, 5444:22, 5447:23, 5448:2, 5448:8, 5455:5, 5456:8, 5456:11, 5461:10, 5462:4, 5465:24, 5479:12, 5481:7, 5482:4, 5482:5, 5482:24, 5489:24, 5610:2, 5610:5, 5610:7,

5610:11
side's [1] - 5522:15
sidebar [5] - 5421:15, 5495:20, 5524:24, 5616:21, 5649:22
Sidebar [11] - 5421:16, 5422:14, 5494:18, 5497:6, 5524:25, 5527:1, 5583:25, 5586:14, 5616:23, 5619:5, 5651:13
sides [4] - 5392:20, 5394:16, 5552:18, 5655:9
sign [1] - 5406:22
signed [3] - 5691:3, 5691:8, 5718:8
significance [1] - 5450:12
significant [12] - 5433:16, 5435:17, 5436:4, 5442:14, 5442:21, 5453:12, 5458:14, 5549:25, 5557:16, 5630:8, 5706:15
significantly [4] - 5427:18, 5433:13, 5433:15, 5434:10
Sikorski [1] - 5673:11
silence [1] - 5386:3
Sillup [11] - 5529:19, 5529:20, 5530:2, 5530:7, 5530:10, 5530:16, 5530:18, 5531:9, 5531:11, 5621:13
similar [10] - 5394:20, 5415:12, 5445:13, 5469:4, 5588:12, 5627:9, 5627:15, 5627:24, 5646:5, 5702:22
similarly [4] - 5415:12, 5533:8, 5565:14, 5566:4
simple [7] - 5420:17, 5431:3, 5437:11, 5441:2, 5446:1, 5460:9, 5518:10
simply [1] - 5646:21
simultaneous [1] - 5383:3
single [31] - 5499:9, 5520:16, 5521:5, 5521:7, 5527:19, 5528:20, 5529:14, 5531:16, 5532:10, 5533:3, 5533:8,

5535:21, 5540:12, 5540:24, 5541:4, 5541:13, 5562:6, 5564:2, 5564:12, 5565:23, 5566:14, 5566:21, 5567:2, 5568:12, 5568:25, 5603:19, 5603:20, 5605:6, 5607:10, 5624:11, 5679:15
sit [6] - 5384:5, 5386:22, 5472:12, 5679:14, 5702:20, 5720:2
sitting [9] - 5386:24, 5509:8, 5509:21, 5511:20, 5521:14, 5524:1, 5571:2, 5588:7, 5701:13
situated [1] - 5399:9
situation [3] - 5667:6, 5683:6, 5684:17
six [3] - 5448:24, 5449:2, 5539:25
size [13] - 5410:20, 5437:22, 5445:11, 5468:13, 5551:3, 5552:4, 5556:3, 5626:16, 5627:25, 5628:1, 5631:19, 5694:9
SKADDEN [1] - 5378:19
skills [2] - 5697:13, 5704:25
skip [2] - 5412:17, 5713:21
SLATE [1] - 5378:19
sleep [2] - 5402:19, 5452:23
slide [44] - 5428:9, 5430:4, 5433:18, 5434:8, 5442:7, 5465:19, 5468:16, 5471:1, 5478:25, 5492:3, 5498:10, 5504:8, 5507:7, 5507:13, 5512:3, 5512:10, 5512:13, 5512:25, 5513:14, 5579:16, 5596:24, 5628:25, 5679:9, 5679:12, 5679:15, 5679:19, 5680:2, 5683:17, 5683:20, 5684:4, 5684:5, 5685:19, 5685:20, 5689:24, 5702:9, 5704:23, 5705:6, 5706:10, 5713:10,

5717:7, 5717:8
Slide [9] - 5458:24, 5460:16, 5482:3, 5528:1, 5596:25, 5598:7, 5706:5, 5713:2, 5713:22
slides [15] - 5543:20, 5544:4, 5544:8, 5544:11, 5544:13, 5610:24, 5681:6, 5681:7, 5681:13, 5683:1, 5683:13, 5684:2, 5684:9, 5684:14, 5712:25
slipped [1] - 5638:24
slow [1] - 5391:10
slowing [1] - 5392:24
small [14] - 5432:2, 5455:25, 5504:3, 5599:10, 5604:4, 5627:14, 5627:22, 5631:19, 5676:21, 5676:24, 5691:14, 5693:17, 5707:20, 5707:22
smaller [4] - 5435:25, 5557:4, 5598:21, 5599:16
smarter [1] - 5552:20
Smith [2] - 5660:16, 5660:18
so.. [3] - 5455:13, 5496:19, 5499:23
socioeconomic [1] - 5517:22
solicit [1] - 5406:11
solitary [1] - 5564:20
Somacia [2] - 5534:2, 5534:4
someone [17] - 5466:2, 5502:14, 5509:22, 5510:4, 5569:17, 5642:18, 5648:15, 5681:19, 5681:20, 5684:19, 5685:20, 5692:22, 5693:13, 5693:17, 5701:23, 5706:17
something's [1] - 5580:1
sometime [3] - 5383:25, 5394:4, 5496:22
sometimes [10] - 5414:21, 5455:3, 5459:14, 5509:6, 5509:15, 5532:23, 5640:24, 5680:21, 5704:16, 5704:24
somewhere [3] -

5539:25, 5603:15, 5603:16
soon [2] - 5393:19, 5393:25
sorry [72] - 5383:12, 5398:18, 5398:19, 5405:3, 5418:24, 5421:4, 5421:10, 5421:17, 5424:22, 5427:2, 5430:1, 5433:25, 5434:12, 5435:24, 5437:12, 5438:16, 5439:25, 5447:16, 5450:21, 5453:11, 5454:8, 5454:16, 5456:11, 5457:1, 5471:1, 5477:22, 5480:9, 5483:12, 5492:11, 5493:4, 5495:17, 5495:25, 5504:17, 5511:24, 5512:22, 5516:23, 5525:1, 5526:17, 5536:20, 5538:22, 5548:19, 5549:3, 5553:10, 5556:7, 5566:8, 5580:25, 5581:19, 5583:22, 5584:1, 5592:24, 5593:14, 5594:13, 5599:14, 5600:11, 5608:23, 5643:6, 5668:1, 5671:25, 5672:2, 5678:15, 5683:7, 5692:4, 5695:9, 5695:11, 5696:5, 5696:6, 5697:2, 5702:14, 5713:2, 5715:2
sort [14] - 5382:5, 5382:15, 5389:4, 5393:20, 5505:24, 5507:15, 5565:18, 5567:18, 5567:21, 5671:10, 5694:9, 5695:22, 5699:13, 5706:9
sorts [2] - 5704:18, 5713:5
Soule [2] - 5378:23, 5723:11
Soule@njd.uscourts .gov [1] - 5378:24
sound [4] - 5533:25, 5556:22, 5620:2, 5631:8
sounded [1] - 5690:15
sounds [8] - 5407:16, 5435:15, 5440:25,

5445:24, 5583:17, 5587:15, 5637:9, 5709:13
sources [2] - 5418:1, 5570:23
space [3] - 5672:21, 5674:5, 5674:16
spare [1] - 5440:24
speaker [151] - 5424:12, 5425:15, 5425:16, 5425:22, 5425:24, 5429:16, 5430:8, 5437:5, 5440:5, 5443:9, 5444:3, 5451:22, 5451:23, 5460:6, 5467:12, 5468:7, 5470:15, 5470:16, 5471:7, 5471:22, 5473:5, 5473:22, 5474:13, 5474:21, 5475:4, 5475:16, 5476:7, 5477:14, 5477:24, 5479:2, 5479:19, 5479:21, 5480:2, 5490:11, 5498:24, 5498:25, 5499:3, 5499:8, 5508:17, 5522:18, 5541:22, 5542:1, 5542:2, 5542:8, 5542:24, 5543:14, 5543:15, 5544:15, 5544:16, 5544:21, 5545:6, 5546:10, 5546:13, 5549:16, 5573:11, 5575:15, 5578:7, 5590:25, 5597:9, 5613:16, 5645:6, 5645:9, 5645:12, 5646:2, 5647:16, 5665:19, 5674:11, 5676:9, 5676:16, 5676:17, 5676:18, 5676:23, 5676:24, 5678:3, 5678:9, 5678:18, 5680:14, 5681:8, 5681:13, 5681:19, 5682:25, 5683:12, 5684:9, 5684:20, 5684:23, 5685:9, 5685:11, 5685:13, 5685:25, 5688:16, 5689:5, 5689:8, 5690:19, 5691:2, 5691:5, 5691:8, 5691:13, 5691:14, 5691:25, 5692:5, 5692:10, 5692:13, 5692:14, 5693:10,

5693:12, 5694:8,
5694:12, 5695:23,
5697:4, 5697:8,
5697:19, 5699:22,
5699:24, 5700:3,
5700:9, 5700:12,
5700:18, 5701:4,
5701:6, 5703:10,
5703:21, 5705:3,
5705:15, 5706:11,
5706:15, 5706:19,
5706:23, 5707:20,
5708:8, 5708:9,
5708:18, 5709:2,
5709:4, 5709:5,
5709:14, 5709:24,
5710:3, 5711:23,
5713:7, 5713:11,
5713:18, 5713:24,
5714:20, 5715:25,
5716:14, 5716:19,
5716:25, 5717:6,
5717:15, 5717:24
Speaker [16] -
5424:14, 5424:19,
5430:9, 5436:23,
5459:2, 5460:6,
5475:7, 5596:4,
5677:12, 5677:22,
5699:2, 5706:2,
5706:8, 5710:23,
5712:13, 5716:19
speaker's [1] - 5683:1
speakers [120] -
5408:19, 5408:22,
5408:24, 5409:16,
5410:25, 5411:13,
5420:13, 5423:24,
5424:19, 5425:21,
5426:1, 5426:3,
5428:5, 5428:18,
5428:21, 5429:22,
5430:15, 5430:17,
5430:18, 5433:5,
5433:11, 5433:12,
5433:13, 5433:23,
5434:1, 5434:10,
5434:13, 5434:14,
5435:12, 5436:7,
5436:8, 5436:18,
5436:22, 5436:23,
5436:25, 5437:5,
5437:13, 5438:24,
5439:1, 5440:15,
5450:25, 5451:1,
5451:4, 5451:21,
5452:1, 5452:2,
5452:5, 5452:20,
5452:25, 5456:13,
5457:17, 5459:1,
5459:16, 5459:20,

5460:1, 5460:17,
5465:3, 5477:13,
5477:14, 5479:2,
5479:6, 5480:2,
5490:11, 5542:5,
5573:1, 5573:6,
5590:21, 5613:19,
5678:23, 5679:6,
5679:24, 5680:5,
5680:25, 5681:7,
5683:17, 5684:1,
5684:3, 5684:14,
5684:22, 5685:17,
5687:8, 5690:3,
5691:7, 5692:20,
5694:23, 5695:24,
5696:3, 5696:9,
5696:14, 5696:15,
5697:18, 5698:4,
5698:15, 5698:23,
5699:3, 5700:4,
5700:10, 5701:1,
5702:23, 5703:14,
5703:20, 5704:6,
5704:13, 5705:5,
5707:13, 5707:16,
5708:2, 5709:7,
5710:13, 5710:24,
5711:5, 5711:7,
5711:13, 5711:19,
5714:8, 5714:15,
5715:10, 5717:13
Speakers [6] -
5428:10, 5458:24,
5681:5, 5685:8,
5699:14, 5704:5
speakers' [7] -
5409:22, 5420:14,
5426:14, 5430:14,
5436:17, 5458:21,
5590:22
speaking [45] -
5416:7, 5416:10,
5416:11, 5416:14,
5423:18, 5424:14,
5424:19, 5425:5,
5429:16, 5444:3,
5446:16, 5452:19,
5454:11, 5454:13,
5459:2, 5466:21,
5466:22, 5500:14,
5500:17, 5535:18,
5542:13, 5542:20,
5542:23, 5549:16,
5574:4, 5575:20,
5575:21, 5576:21,
5577:21, 5591:1,
5598:1, 5599:10,
5602:9, 5605:21,
5608:12, 5685:17,
5685:25, 5687:8,

5690:12, 5700:2,
5704:7, 5721:15
Spear [1] - 5478:13
Spear-over [1] -
5478:13
Spearman [3] -
5440:25, 5458:2,
5478:10
Spearman's [1] -
5440:24
special [2] - 5444:19,
5671:19
specialists [5] -
5554:18, 5554:20,
5555:16, 5557:18,
5673:4
specialize [2] -
5410:21, 5690:20
specialized [1] -
5404:15
specialty [2] -
5631:11, 5697:12
specific [5] - 5465:21,
5498:4, 5539:11,
5612:21, 5648:18
specifically [4] -
5458:21, 5459:13,
5647:12, 5655:7
speculating [1] -
5664:14
speech [6] - 5420:16,
5420:19, 5479:24,
5575:25, 5576:1
speeches [1] -
5699:21
spelling [4] - 5398:17,
5398:19, 5635:25,
5671:3
spells [1] - 5382:13
spend [4] - 5394:21,
5408:21, 5444:16,
5496:16
spending [2] -
5441:15, 5699:25
spent [2] - 5458:8,
5710:4
spoken [2] - 5559:12,
5685:25
sponsors [6] -
5513:18, 5513:24,
5514:3, 5514:12,
5514:18, 5518:14
spot [2] - 5557:25,
5704:19
spreadsheet [1] -
5702:17
spreadsheets [1] -
5697:4
Square [1] - 5378:21
staff [4] - 5700:8,

5700:23, 5701:3,
5701:8
stage [1] - 5704:19
stages [1] - 5402:14
stand [5] - 5532:6,
5536:14, 5616:5,
5635:6, 5635:19
standard [1] - 5658:10
standby [2] - 5721:18,
5722:6
start [15] - 5401:22,
5426:18, 5470:21,
5494:19, 5571:13,
5573:23, 5598:14,
5603:15, 5603:16,
5636:8, 5636:21,
5636:22, 5657:25,
5676:17, 5694:12
started [20] - 5380:24,
5384:1, 5401:24,
5403:23, 5404:13,
5410:23, 5423:4,
5587:18, 5591:1,
5591:4, 5594:9,
5594:17, 5603:25,
5654:4, 5656:19,
5663:11, 5673:17,
5675:14, 5675:15,
5675:25
starting [3] - 5405:6,
5595:6, 5676:19
starts [1] - 5396:22
startups [1] - 5404:4
State [1] - 5378:9
state [21] - 5389:24,
5390:7, 5391:25,
5398:16, 5428:9,
5435:22, 5510:12,
5543:5, 5581:16,
5581:20, 5581:21,
5581:22, 5582:5,
5601:18, 5615:19,
5635:24, 5671:2,
5685:22, 5708:14,
5708:19, 5708:25
statement [11] -
5417:24, 5450:13,
5475:25, 5501:1,
5514:21, 5540:23,
5545:4, 5545:9,
5556:21, 5621:15,
5714:4
statements [1] -
5463:10
states [6] - 5450:16,
5473:7, 5476:13,
5581:20, 5581:24,
5582:4
STATES [3] - 5378:1,
5378:3, 5378:12

States [3] - 5380:2,
5517:11, 5517:19
stating [1] - 5391:8
statistic [1] - 5624:11
statistical [24] -
5420:7, 5431:7,
5431:8, 5431:10,
5433:14, 5434:20,
5435:12, 5436:13,
5440:10, 5440:18,
5449:12, 5449:20,
5449:24, 5450:12,
5458:4, 5465:6,
5467:5, 5478:19,
5601:24, 5615:12,
5616:7, 5631:23,
5632:2, 5633:3
statistically [10] -
5410:1, 5433:15,
5435:17, 5435:18,
5436:3, 5442:14,
5442:21, 5450:8,
5453:11, 5557:16
statisticals [1] -
5430:22
statistician [1] -
5625:17
statistics [34] -
5399:14, 5400:15,
5400:18, 5400:21,
5402:7, 5402:10,
5408:3, 5408:6,
5408:9, 5408:16,
5438:20, 5442:18,
5445:21, 5446:6,
5447:2, 5455:3,
5456:18, 5469:9,
5504:6, 5507:23,
5518:25, 5519:4,
5545:14, 5580:7,
5599:18, 5602:5,
5615:10, 5615:13,
5615:14, 5616:14,
5623:4, 5623:7,
5626:5, 5626:25
stature [1] - 5697:12
Statute [6] - 5412:11,
5596:10, 5612:1,
5612:5, 5612:15,
5613:1
stay [4] - 5408:7,
5516:20, 5618:21,
5685:8
staying [1] - 5618:16
stays [1] - 5389:6
steak [2] - 5594:25,
5615:3
stenography [1] -
5378:25
step [4] - 5418:21,

tendency [4] -
5449:15, 5452:21,
5622:7
tenure [1] - 5402:24
term [2] - 5463:9,
5692:9
terms [25] - 5390:19,
5410:4, 5412:17,
5429:15, 5440:15,
5467:16, 5467:17,
5496:5, 5499:14,
5505:25, 5510:18,
5515:13, 5515:23,
5516:24, 5518:19,
5535:13, 5599:7,
5640:7, 5700:4,
5703:13, 5703:19,
5715:16, 5716:13,
5717:12
terribly [1] - 5671:15
test [44] - 5433:15,
5434:24, 5435:6,
5435:8, 5435:10,
5436:6, 5440:10,
5440:13, 5440:18,
5441:1, 5441:3,
5441:5, 5441:7,
5441:18, 5441:19,
5441:24, 5441:25,
5442:6, 5442:13,
5442:22, 5442:24,
5449:12, 5449:20,
5449:21, 5449:24,
5450:3, 5450:4,
5450:5, 5450:7,
5450:11, 5452:8,
5453:8, 5458:2,
5458:3, 5458:4,
5458:7, 5632:7,
5632:8, 5633:3,
5658:20, 5663:9
tested [2] - 5435:8,
5451:9
testified [54] - 5398:5,
5406:3, 5406:12,
5407:19, 5413:18,
5496:21, 5521:6,
5521:20, 5521:24,
5523:4, 5523:8,
5523:19, 5523:25,
5528:2, 5529:19,
5529:20, 5530:2,
5530:10, 5531:17,
5532:18, 5532:19,
5532:23, 5533:3,
5533:7, 5533:8,
5533:13, 5534:1,
5535:2, 5535:4,
5535:6, 5536:22,
5538:1, 5538:20,

5551:12, 5567:7,
5571:3, 5574:7,
5578:4, 5585:14,
5585:21, 5604:19,
5605:11, 5605:16,
5607:1, 5610:14,
5620:16, 5621:20,
5637:23, 5643:4,
5643:7, 5644:9,
5645:7, 5646:9,
5649:16
TESTIFIED [3] -
5398:15, 5635:22,
5670:25
testifies [1] - 5394:11
testify [8] - 5405:24,
5522:24, 5523:23,
5541:4, 5541:13,
5541:19, 5595:13,
5609:1
testifying [12] -
5421:7, 5468:3,
5469:8, 5475:20,
5512:6, 5567:12,
5578:10, 5578:19,
5591:5, 5608:11,
5621:21, 5665:8
testimonies [3] -
5464:24, 5533:18,
5538:5
testimony [116] -
5392:24, 5393:5,
5393:8, 5393:10,
5394:3, 5394:24,
5395:11, 5395:13,
5399:13, 5406:7,
5413:15, 5413:17,
5427:23, 5445:18,
5464:25, 5465:5,
5465:11, 5496:2,
5496:22, 5501:23,
5508:23, 5509:8,
5509:16, 5510:3,
5512:3, 5512:4,
5520:22, 5520:23,
5521:12, 5522:10,
5522:20, 5523:13,
5524:6, 5527:23,
5528:1, 5528:7,
5528:14, 5528:15,
5529:8, 5529:23,
5530:14, 5531:18,
5533:15, 5534:11,
5534:13, 5534:14,
5535:22, 5536:8,
5536:10, 5536:13,
5536:23, 5537:11,
5537:12, 5539:6,
5540:4, 5543:25,
5551:4, 5551:5,

5563:23, 5570:22,
5570:25, 5571:6,
5574:13, 5574:20,
5584:5, 5585:23,
5589:24, 5593:23,
5595:20, 5603:23,
5604:18, 5604:21,
5605:6, 5605:24,
5606:3, 5606:10,
5606:19, 5607:11,
5607:23, 5608:21,
5608:24, 5609:3,
5609:4, 5609:9,
5609:19, 5609:22,
5610:12, 5610:21,
5614:24, 5619:25,
5635:11, 5635:21,
5642:25, 5644:10,
5644:12, 5644:16,
5644:20, 5645:4,
5645:5, 5645:17,
5646:13, 5647:1,
5647:6, 5647:7,
5648:21, 5649:3,
5649:20, 5649:25,
5650:9, 5652:8,
5653:16, 5659:17,
5666:9, 5670:5,
5713:16
Texas [2] - 5378:17,
5701:19
thanking [2] - 5663:1,
5664:6
that'd [1] - 5720:16
THE [241] - 5378:1,
5378:11, 5380:4,
5380:5, 5380:16,
5380:22, 5381:8,
5381:11, 5381:16,
5382:7, 5382:9,
5382:18, 5382:20,
5382:25, 5383:3,
5383:15, 5383:19,
5383:22, 5384:3,
5384:13, 5384:25,
5385:3, 5385:15,
5385:19, 5385:21,
5385:23, 5386:1,
5386:6, 5386:8,
5386:11, 5387:4,
5387:7, 5387:19,
5387:21, 5388:5,
5388:13, 5388:16,
5388:22, 5389:2,
5389:18, 5390:17,
5390:24, 5391:14,
5392:2, 5392:7,
5392:10, 5392:22,
5393:3, 5393:12,
5393:24, 5394:2,
5394:8, 5394:12,

5395:8, 5395:24,
5396:2, 5396:14,
5396:19, 5396:24,
5397:2, 5397:5,
5397:16, 5397:17,
5397:20, 5397:23,
5397:24, 5398:13,
5398:16, 5398:18,
5398:19, 5398:21,
5398:22, 5421:2,
5421:3, 5421:6,
5421:8, 5421:15,
5421:17, 5421:24,
5422:13, 5463:13,
5463:16, 5463:21,
5463:24, 5464:1,
5464:3, 5464:8,
5464:9, 5494:7,
5494:12, 5494:16,
5494:20, 5495:1,
5495:4, 5495:9,
5495:13, 5495:18,
5496:6, 5496:20,
5496:25, 5497:9,
5499:24, 5506:23,
5506:25, 5507:3,
5517:6, 5524:24,
5525:3, 5525:14,
5526:8, 5526:11,
5526:13, 5526:18,
5526:21, 5526:25,
5527:4, 5537:14,
5537:15, 5537:16,
5537:18, 5537:19,
5537:21, 5547:20,
5547:23, 5548:18,
5548:19, 5558:1,
5558:3, 5559:3,
5559:5, 5559:7,
5559:9, 5583:24,
5584:1, 5584:4,
5584:7, 5584:11,
5584:15, 5584:18,
5585:2, 5585:20,
5586:2, 5586:9,
5586:17, 5593:9,
5593:10, 5593:15,
5593:21, 5593:22,
5593:24, 5613:4,
5616:19, 5616:22,
5616:24, 5617:4,
5617:12, 5617:15,
5617:18, 5617:22,
5618:1, 5618:5,
5618:8, 5618:17,
5618:21, 5618:23,
5619:1, 5619:4,
5619:7, 5629:4,
5633:17, 5633:19,
5633:21, 5634:1,
5634:6, 5634:8,

5634:10, 5634:19,
5634:23, 5635:1,
5635:2, 5635:4,
5635:7, 5635:10,
5635:13, 5635:14,
5635:16, 5635:20,
5635:24, 5636:1,
5636:2, 5638:17,
5649:21, 5650:3,
5650:6, 5650:11,
5650:13, 5650:19,
5650:23, 5651:1,
5651:4, 5651:10,
5651:16, 5652:24,
5668:8, 5668:11,
5670:9, 5670:11,
5670:12, 5670:16,
5670:20, 5671:2,
5671:4, 5677:16,
5682:17, 5686:8,
5686:11, 5686:15,
5686:18, 5686:20,
5686:21, 5686:23,
5686:24, 5687:1,
5688:6, 5705:22,
5712:21, 5716:10,
5719:5, 5719:8,
5719:11, 5719:20,
5719:22, 5720:6,
5720:15, 5720:17,
5721:19, 5721:23,
5722:7, 5722:11,
5722:14, 5722:17
theme [1] - 5682:23
themselves [11] -
5404:10, 5404:23,
5407:6, 5428:5,
5433:12, 5452:20,
5475:4, 5479:3,
5549:16, 5563:22,
5710:13
theory [3] - 5531:5,
5564:19, 5573:18
therapeutic [4] -
5675:9, 5676:21,
5708:1, 5708:4
Therapeutic [1] -
5637:7
Therapeutics [3] -
5636:15, 5660:13,
5683:16
they've [4] - 5389:23,
5541:13, 5590:4,
5591:10
thinking [1] - 5525:17
thinks [1] - 5613:2
third [20] - 5427:7,
5429:4, 5439:13,
5439:18, 5451:25,
5452:24, 5457:10,

5461:18, 5461:19, 5468:25, 5470:11, 5475:10, 5481:15, 5604:3, 5604:16, 5628:5, 5666:18, 5699:13, 5722:8
third-party [2] - 5468:25, 5666:18
thirds [4] - 5427:14, 5593:1, 5627:13, 5699:13
thousand [9] - 5416:14, 5426:19, 5434:7, 5455:18, 5455:24, 5467:23, 5468:7, 5601:14, 5601:15
thousand-plus [1] - 5601:14
thousands [12] - 5419:25, 5443:17, 5443:19, 5443:25, 5444:2, 5445:3, 5450:10, 5452:5, 5503:24, 5539:25, 5597:11, 5708:2
threat [2] - 5558:22, 5559:11
three [21] - 5385:24, 5403:23, 5409:7, 5417:14, 5437:13, 5439:4, 5439:10, 5452:3, 5456:6, 5471:16, 5567:2, 5567:23, 5597:10, 5597:14, 5602:12, 5626:3, 5699:15, 5699:21, 5701:5, 5717:1
threshold [1] - 5386:14
throughout [4] - 5487:9, 5632:19, 5633:13, 5709:9
thumb [1] - 5621:3
Thursday [1] - 5389:10
Tibotec [11] - 5605:17, 5658:5, 5673:1, 5673:5, 5673:12, 5673:22, 5676:5, 5676:19, 5676:23, 5677:22, 5683:16
Tibotec's [2] - 5674:11, 5707:19
tied [1] - 5637:17
tight [1] - 5720:10
tiny [2] - 5673:11, 5673:14
title [1] - 5425:15

titled [1] - 5710:23
Titusville [1] - 5662:1
tobacco [6] - 5616:15, 5617:2, 5617:8, 5617:19, 5618:7, 5618:9
today [27] - 5384:8, 5388:11, 5391:17, 5394:3, 5395:2, 5395:13, 5398:4, 5399:8, 5399:14, 5519:4, 5546:9, 5552:17, 5556:25, 5586:9, 5588:1, 5630:6, 5631:10, 5634:18, 5636:19, 5653:10, 5653:11, 5653:20, 5653:21, 5653:22, 5653:24, 5719:13, 5721:25
together [6] - 5471:1, 5473:3, 5627:3, 5694:16, 5701:25
tomorrow [13] - 5381:21, 5394:4, 5394:5, 5395:14, 5396:5, 5436:2, 5719:14, 5719:16, 5719:23, 5720:7, 5720:18, 5721:2, 5721:11
tonight [10] - 5385:2, 5385:21, 5386:13, 5394:6, 5395:14, 5396:4, 5720:20, 5720:24, 5721:17
Tony [7] - 5641:2, 5649:8, 5657:11, 5657:13, 5659:24, 5668:5, 5668:6
took [15] - 5439:3, 5447:15, 5461:11, 5488:13, 5488:14, 5507:14, 5563:4, 5564:7, 5565:6, 5567:21, 5589:1, 5613:15, 5669:19, 5672:17, 5684:14
tools [1] - 5518:13
top [22] - 5436:12, 5436:23, 5439:8, 5439:18, 5439:20, 5440:15, 5443:16, 5454:7, 5457:9, 5458:24, 5461:2, 5466:9, 5482:6, 5505:17, 5506:2, 5507:20, 5508:1, 5508:16, 5599:20, 5614:4, 5708:21

topic [9] - 5404:18, 5463:14, 5557:25, 5569:7, 5618:4, 5618:24, 5619:9, 5652:18, 5719:9
topics [6] - 5543:4, 5543:5, 5559:24, 5608:3, 5706:9, 5722:1
topping [1] - 5477:1
Toronto [3] - 5671:21, 5671:22, 5672:17
total [40] - 5408:20, 5409:9, 5409:21, 5411:23, 5414:4, 5414:7, 5415:16, 5424:13, 5425:4, 5425:7, 5425:10, 5425:12, 5447:15, 5451:8, 5451:10, 5466:14, 5473:12, 5473:13, 5480:17, 5484:2, 5489:10, 5492:7, 5492:12, 5492:24, 5493:7, 5493:15, 5493:23, 5495:2, 5495:4, 5507:25, 5539:14, 5544:7, 5589:9, 5589:21, 5599:8, 5600:18, 5627:5, 5713:11, 5714:5
totaled [1] - 5487:19
totally [3] - 5475:9, 5622:20
totals [3] - 5485:2, 5486:5, 5550:6
touch [5] - 5620:24, 5621:2, 5625:15, 5656:2, 5673:10
tough [2] - 5596:21, 5674:18
track [2] - 5395:6, 5706:11
tracked [1] - 5717:13
trade [2] - 5473:12, 5474:15
train [5] - 5677:1, 5694:23, 5699:3, 5699:25, 5704:15
trained [6] - 5642:17, 5680:6, 5685:19, 5690:3, 5704:6
training [25] - 5425:5, 5492:6, 5492:20, 5493:10, 5493:20, 5494:2, 5683:20, 5689:5, 5691:3, 5691:5, 5691:8, 5699:25, 5700:1,

5704:8, 5704:13, 5704:18, 5705:2, 5705:15, 5706:2, 5706:16, 5707:10, 5716:19, 5716:20, 5716:21, 5717:24
Training [1] - 5704:5
trainings [2] - 5689:17, 5706:23
transcript [11] - 5378:25, 5393:19, 5393:25, 5394:3, 5394:7, 5524:12, 5524:14, 5524:16, 5604:22, 5605:3, 5723:4
transcription [1] - 5378:25
transcripts [1] - 5588:8
transferring [1] - 5398:4
translate [1] - 5429:3
transparent [1] - 5472:6
traumatizing [1] - 5639:7
travel [2] - 5689:8, 5701:23
traveled [1] - 5570:2
treat [3] - 5551:7, 5569:12, 5708:22
treatment [33] - 5412:19, 5413:4, 5415:8, 5415:14, 5418:15, 5419:13, 5419:15, 5481:11, 5481:12, 5481:15, 5481:17, 5481:20, 5486:5, 5486:11, 5486:20, 5486:22, 5486:23, 5487:3, 5487:18, 5488:9, 5489:1, 5535:6, 5535:8, 5535:15, 5535:19, 5535:23, 5538:2, 5538:9, 5674:17, 5699:7, 5708:20
treatment-experienced [2] - 5486:23, 5487:3
treatment-naive [23] - 5415:8, 5418:15, 5419:13, 5419:15, 5481:11, 5481:12, 5481:15, 5481:17, 5481:20, 5486:5, 5486:11, 5486:20, 5486:22, 5487:18,

5488:9, 5489:1, 5535:6, 5535:8, 5535:15, 5535:19, 5535:23, 5538:2, 5538:9
trenches [1] - 5703:16
trend [5] - 5457:14, 5597:12, 5597:14, 5615:24, 5624:12
trends [3] - 5615:12, 5632:18, 5633:4
Trenton [1] - 5378:9
trial [33] - 5388:10, 5391:10, 5395:6, 5398:7, 5465:5, 5487:9, 5513:15, 5524:8, 5524:16, 5524:17, 5528:16, 5528:20, 5529:10, 5541:12, 5558:16, 5588:7, 5588:8, 5594:17, 5605:3, 5606:3, 5609:18, 5616:5, 5633:18, 5634:3, 5636:7, 5637:21, 5643:7, 5644:6, 5670:10, 5708:7, 5709:20, 5710:16
TRIAL [1] - 5378:5
trials [1] - 5693:4
tried [5] - 5405:15, 5555:22, 5556:10, 5557:17, 5641:2
trouble [3] - 5595:17, 5655:6, 5667:13
true [11] - 5453:17, 5472:2, 5514:14, 5541:15, 5546:20, 5546:21, 5552:23, 5649:11, 5652:15, 5666:7, 5715:11
truly [1] - 5515:17
trust [1] - 5648:5
truth [2] - 5497:15, 5532:5
truthful [1] - 5647:2
truthfully [1] - 5576:10
try [11] - 5399:9, 5399:11, 5432:1, 5435:3, 5437:7, 5487:1, 5487:2, 5521:19, 5538:14, 5557:19, 5667:9
trying [17] - 5404:10, 5423:6, 5423:7, 5496:16, 5525:9, 5525:20, 5555:14, 5575:3, 5575:5, 5577:9, 5585:9,

5585:11, 5591:20,
5625:18, 5641:20,
5649:25, 5650:17
TTU.S [2] - 5675:20
turn [16] - 5408:13,
5415:5, 5415:20,
5419:11, 5433:7,
5434:9, 5437:25,
5478:18, 5480:25,
5522:14, 5592:22,
5596:25, 5627:5,
5627:8, 5628:12,
5628:16
turned [2] - 5392:13,
5485:17
turns [1] - 5474:1
Turrett [7] - 5524:9,
5524:15, 5527:6,
5527:11, 5527:21,
5528:4, 5529:8
twice [7] - 5439:16,
5490:15, 5490:19,
5624:19, 5626:13,
5661:25
two [88] - 5381:6,
5385:24, 5385:25,
5401:25, 5408:18,
5408:25, 5409:7,
5409:25, 5412:8,
5414:22, 5415:3,
5415:21, 5427:7,
5427:14, 5431:13,
5435:6, 5437:22,
5442:4, 5444:7,
5444:13, 5444:24,
5445:10, 5445:12,
5445:13, 5446:12,
5446:13, 5450:13,
5453:10, 5453:11,
5456:1, 5461:18,
5461:19, 5482:1,
5487:4, 5487:14,
5487:15, 5498:1,
5505:17, 5506:2,
5506:7, 5507:20,
5507:24, 5508:8,
5508:16, 5512:15,
5526:3, 5528:10,
5532:11, 5533:9,
5537:8, 5541:1,
5551:17, 5551:20,
5552:13, 5554:25,
5555:9, 5555:23,
5556:2, 5556:3,
5556:24, 5557:3,
5557:13, 5557:16,
5557:20, 5566:22,
5576:14, 5593:1,
5597:10, 5597:14,
5602:12, 5608:9,

5614:4, 5614:14,
5627:13, 5627:24,
5647:7, 5660:15,
5661:21, 5663:1,
5675:23, 5689:20,
5690:18, 5699:13,
5701:5, 5711:15,
5721:18
two-third [3] - 5427:7,
5461:18, 5461:19
two-thirds [4] -
5427:14, 5593:1,
5627:13, 5699:13
Tylenol [1] - 5409:12
type [10] - 5403:21,
5406:6, 5464:23,
5576:15, 5616:2,
5630:24, 5641:18,
5641:21, 5713:6
types [6] - 5407:14,
5503:12, 5640:15,
5641:15, 5642:7,
5708:8
typical [30] - 5431:11,
5431:12, 5432:15,
5432:19, 5433:7,
5433:20, 5434:15,
5447:24, 5448:10,
5448:14, 5448:15,
5448:16, 5448:18,
5448:23, 5451:10,
5451:11, 5451:15,
5451:17, 5451:23,
5453:4, 5456:5,
5466:20, 5466:22,
5467:5, 5469:5,
5469:6, 5602:8
typically [7] - 5587:4,
5677:1, 5701:6,
5706:17, 5707:11,
5708:20, 5713:6
typo [1] - 5455:9

U

U.S [8] - 5378:8,
5399:18, 5406:16,
5409:14, 5515:8,
5525:3, 5707:24,
5709:9
ultimately [10] -
5403:4, 5414:2,
5426:7, 5487:18,
5613:23, 5618:15,
5681:1, 5694:1,
5694:20, 5702:24
umbrella [1] - 5612:9
unapproved [1] -
5684:8
unbelievable [1] -

5673:2
unbiased [1] -
5596:20
uncommon [2] -
5558:18, 5558:19
under [20] - 5389:11,
5389:15, 5464:7,
5511:20, 5523:13,
5540:6, 5559:17,
5577:8, 5581:11,
5612:9, 5630:12,
5636:11, 5643:11,
5644:17, 5649:16,
5669:25, 5678:18,
5687:4, 5716:25,
5717:6
undergraduate [1] -
5636:25
understood [10] -
5385:19, 5404:16,
5610:6, 5617:16,
5621:15, 5630:23,
5634:8, 5634:19,
5663:19, 5707:13
undertake [1] -
5382:14
undisclosed [2] -
5494:22, 5495:5
undiscounted [2] -
5628:20, 5629:8
unexcited [1] - 5438:5
unfettered [3] -
5516:20, 5517:23,
5622:13
unfortunately [1] -
5615:14
unhappy [1] - 5640:3
uninfluenced [3] -
5631:14, 5631:17,
5631:20
uninfluenced-only [1]
- 5631:20
unique [5] - 5444:23,
5446:2, 5446:7,
5446:12, 5460:12
United [3] - 5380:2,
5517:11, 5517:19
UNITED [3] - 5378:1,
5378:3, 5378:12
universe [1] - 5484:19
University [14] -
5399:7, 5400:6,
5400:8, 5401:22,
5402:4, 5402:8,
5402:12, 5402:25,
5403:5, 5403:10,
5403:13, 5431:25,
5671:14
unlawful [1] - 5411:24
unless [5] - 5390:15,

5410:21, 5633:7,
5708:20, 5722:3
unlikely [2] - 5452:17,
5570:6
unnecessary [1] -
5617:23
unreasonable [3] -
5520:1, 5520:5,
5520:10
unrelated [2] -
5470:11, 5475:11
unreliable [1] - 5520:2
unsolicited [2] -
5683:2, 5685:12
unusual [8] - 5429:13,
5430:5, 5430:6,
5450:14, 5460:14,
5472:11, 5472:16,
5609:24
up [76] - 5405:7,
5412:2, 5414:18,
5414:20, 5415:2,
5425:21, 5427:10,
5427:11, 5438:6,
5438:19, 5443:15,
5452:25, 5494:22,
5494:25, 5499:9,
5504:7, 5506:7,
5507:1, 5512:24,
5513:16, 5521:19,
5523:17, 5525:6,
5526:22, 5534:16,
5541:18, 5541:21,
5548:14, 5576:6,
5579:16, 5582:23,
5586:3, 5596:24,
5608:4, 5611:22,
5614:16, 5615:4,
5615:5, 5627:5,
5630:21, 5632:24,
5649:2, 5652:8,
5655:24, 5657:16,
5660:7, 5660:25,
5661:25, 5662:25,
5663:2, 5663:5,
5664:6, 5664:21,
5670:22, 5671:10,
5671:12, 5676:18,
5676:24, 5677:6,
5677:12, 5681:1,
5681:24, 5687:12,
5694:12, 5695:23,
5697:2, 5698:21,
5702:1, 5704:23,
5705:8, 5705:24,
5706:17, 5707:4,
5714:23, 5721:20,
5722:9
upset [1] - 5640:16
usable [1] - 5625:11

usage [1] - 5692:12
useful [1] - 5411:15
uses [1] - 5535:5
utility [1] - 5699:24
utilization [1] -
5518:13

V

Valuation [1] -
5405:18
value [15] - 5458:13,
5612:15, 5628:16,
5628:20, 5629:8,
5629:9, 5630:15,
5692:11, 5692:19,
5693:12, 5696:24,
5697:2, 5717:22,
5717:24, 5718:1
valued [2] - 5640:21,
5675:7
varies [1] - 5474:19
varieties [1] - 5630:7
various [4] - 5470:8,
5636:12, 5658:4,
5678:17
vary [1] - 5693:12
vast [3] - 5452:5,
5456:1, 5456:12
vendor [5] - 5689:4,
5689:7, 5690:2,
5693:21
vendors [3] - 5690:15,
5690:18, 5691:12
venue [1] - 5690:22
verbal [2] - 5538:20,
5539:7
verbally [1] - 5395:16
verdict [7] - 5389:15,
5389:16, 5496:4,
5585:4, 5585:6,
5585:7, 5585:11
versa [1] - 5478:12
versus [14] - 5425:16,
5435:8, 5435:9,
5437:5, 5445:1,
5447:11, 5447:22,
5452:20, 5453:6,
5453:9, 5469:6,
5470:19, 5626:13,
5631:20
vetted [2] - 5681:1,
5692:1
via [2] - 5662:23,
5673:2
vice [2] - 5478:12,
5673:11
Victoria [2] - 5671:13,
5671:14
video [6] - 5638:15,

United States District Court
District of New Jersey